

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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| IN RE PHARMACEUTICAL INDUSTRY |) | |
| AVERAGE WHOLESAL PRICE |) | MDL NO. 1456 |
| LITIGATION |) | Civil Action No. 01-12257-PBS |
| |) | Subcategory Case No: 03-10643-PBS |
| THIS DOCUMENT RELATES TO: |) | |
| |) | Judge Patti B. Saris |
| <i>The City of New York, et al.</i> |) | |
| |) | |
| v. |) | |
| |) | |
| <i>Abbott Laboratories, et al.</i> |) | |
| |) | |

**PLAINTIFFS' REPLY LOCAL RULE 56.1 STATEMENT OF UNDISPUTED
MATERIAL FACTS AS TO MYLAN LABORATORIES INC., MYLAN
PHARMACEUTICALS INC., AND UDL LABORATORIES INC.**

Pursuant to Rule 56.1 of the Local Rules of this Court, plaintiffs hereby submit this Reply Statement of Undisputed Material Facts Applicable to Mylan Laboratories Inc., Mylan Pharmaceuticals Inc., and UDL Laboratories Inc. (collectively "Mylan") in support of their Motion for Partial Summary Judgment.

I. MYLAN SPECIFIC FACTS

1. The Mylan Drugs and NDCs that have been examined in connection with this motion are set forth in Exhibit A hereto. This exhibit also sets forth Mylan's Published AWP's and WACs for these Drugs and NDCs, any operative Federal Upper Limits ("FUL") and Mylan's AMPs. The exhibit notes which NDCs are associated with package sizes that could have set the FUL.

RESPONSE:

Mylan does not dispute the first sentence of Plaintiffs' SOF ¶ 1, except avers that defendant Mylan Inc. is a holding company and does not manufacture, market or sell any pharmaceuticals. *See* Declaration of Christopher C. Palermo in Opposition to Plaintiffs' Motion for Partial Summary Judgment as to Mylan Inc., Mylan Pharmaceuticals Inc., and UDL Laboratories, Inc. ("Palermo Decl."), Ex. A (Deposition of Mylan's 30(b)(6) Designee, Brian Roman, dated November 16, 2006 ("Mylan 11/16/06 Dep.)) at 10:9-

11:21; 12:20-22; Ex. B (Deposition of Harry A. Korman, dated 11/26/07 (“Korman 11/26/07 Dep.”)) at 70:9-71:18. Mylan states that Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. have manufactured and/or sold the drugs and NDCs alleged in Exhibit A to Plaintiffs’ SOF.

Mylan disputes the second sentence of Plaintiffs’ SOF ¶ 1. Mylan does not publish Average Wholesale Price (“AWP”) or Wholesale Acquisition Cost (“WAC”), but rather reports its AWP and WACs to third party pricing compendia, such as First DataBank, RedBook and Medi-Span. Palermo Decl., Ex. C (Deposition of Mylan’s 30(b)(6) Designee, David Workman, dated June 26, 2008 (“Mylan 6/26/08 Dep.”)) at 28:19-29:02. The AWP and WACs published by third party pricing compendia, such as First DataBank, may not necessarily reflect the AWP and WACs reported by Mylan. *Id.* at 21:08-22:06. As Mylan’s 30(b)(6) representative, David Workman, testified:

Q: Do you recall any particular event in which Mylan corrected the price that it had in its database in order to reflect the price that was being published on its behalf by one of the pricing compendia?

A. I don’t recall specific instance but I know that we have in the past corrected our database to reflect what was published or what was discussed with a pricing publication.

Id. at 21:08-22:06; *see also* Ex. D (Deposition of Mylan’s 30(b)(6) Designee, Brian Roman, dated July 26, 2006 (“Mylan 7/26/06 Dep.”)) at 104:019-23, 108:12-16 (“there are times when the number that gets published by these publishers isn’t the same as the number that we sent them.”) Plaintiffs’ Exhibit A also incorrectly reports AMP values for several of the Mylan NDCs listed. *See* Plaintiffs’ SOF, Ex. A. In addition, in numerous instances, Exhibit A lists published prices and/or FUL prices after a product’s or price’s effective or obsolete date, and is thus unreliable and unsupported by the evidence cited. *Id.*

Mylan disputes the third sentence of Plaintiffs’ SOF ¶1 and specifically the characterization implicit in the statement “package sizes that could have set the FUL.” The Centers for Medicare and Medicaid Services (“CMS”) exercised considerable discretion in the setting of Federal Upper Limits (“FULs”) for sound policy reasons and routinely chose to disregard lower published prices. Palermo Decl., Ex. E (Deposition of Sue Gaston, dated March 19, 2008 (“Gaston Dep.”)) at 498:16-499:06. Even Plaintiffs concede that “FULs are not automatically set” and that a “manual review” is performed by CMS as part of its process for determining an appropriate FUL. *See* Plaintiffs’ Memorandum of Law in Support of Motion for Partial Summary Judgment on Issues Relating to the Federal Upper Limit and Under New York Social Services Law § 145-B (“Plaintiffs’ FUL Memo of Law”), at 5. As the undisputed record evidence in Defendants’ Joint Rule 56.1 Statement of Facts also makes clear, CMS would at times deviate from the federal regulation by setting FULs based on NDCs that were neither the 100-count nor the most commonly available package size. *See* Defendants’ Rule 56.1 Statement of Facts in Support of Defendants’ Joint Motion for Partial Summary Judgment, at ¶ 22-33.

Lastly, Mylan disputes any values associated with “Direct” price in Plaintiffs’ Exhibit A, because Mylan did not maintain or report a “direct price” during the relevant time period. *See* Palermo Decl., Ex. C (Mylan 6/26/08 Dep.), at 17:02-17:06; 28:16-29:02.

Plaintiffs’ Reply to Statement #1:

Parties agree that the Mylan Drugs and NDCs set forth in Exhibit A are the drugs and NDCs at issue on this motion and are manufactured and/or sold by Mylan Pharmaceuticals Inc. and UDL Laboratories.

The parties agree further that Mylan reports AWP and WAC to the compendia, such as First DataBank, RedBook, and Medi-Span.

Mylan’s dispute that the data in Exhibit A is not properly supported by record evidence is baseless. Plaintiffs properly cited MYLAN as the source of the Mylan AMP data and the First Databank NDDF data file (Alabama Production, FDB-AWP 030785 – 030795) as the source of all other data (*see* Exhibit A at 28), which is the same source cited by Mylan’s expert Dr. Addanki. *See* Affidavit of Dr. Sumanth Addanki dated May 15, 2009 [Dkt# 6056] at Exhibit 2 (identifying “First DataBank (Alabama Production) Data and NDDF (National Drug Data File)TM Documentation Manual (Rev. April 2000)” as a Data source). *See also* Reply Affidavit of Joanne M. Cicala, sworn to June 30, 2009 and submitted in further support of plaintiffs’ motion for partial summary judgment at ¶2, which is incorporated herein.

Mylan disputes that Exhibit A is accurate and/or complete but offers no evidence in support as required by Rule 56.1. Mylan’s other objections concerning admissibility are likewise baseless and unsubstantiated.

The parties agree that AWP, WAC and/or FUL prices at times appeared in the publishing Compendia after a product’s or prices effective or obsolete date.

Mylan does not specifically dispute that these are “package sizes that could have set the FUL.”

Mylan’s dispute that it did not maintain Direct Prices is contrary to the record evidence testimony of Robert Cunard, stating “[y]es we used direct price. But I believe this term ‘DP’ is taken from the Red Book, which – which may have a different definition than what internally we used.” *See* Cunard 10/26/07 (“Reply Exhibit A” attached hereto) Dep. at 152:18-21; *see also* Cunard 10/30/08 (“Reply Exhibit B” attached hereto) Dep. at 209:10-17 (“Q. Okay. Did the pricing committee ever make any decisions or recommendations regarding average wholesale prices? A. Not that I recall. Q. How about wholesale acquisition costs? A. Yes. Q. How about direct prices? A. Yes.”); *see also* Deposition of Joseph Duda, dated April 16, 2008, (“Duda 4/16/08 Dep.”) (“Reply Exhibit C” attached hereto) at 144:14-18 (“Q. When you were head of contracts and pricing, you knew both the average wholesale price and the direct prices; is that correct? A. I had a reference where I could look at the two prices, yes.”).

In further response, the parties agree that Mylan Inc. was formerly known as Mylan Laboratories Inc. *See* Mylan’s Local Rule 56.1 Statement In Opposition to Plaintiffs’ Local Rule 56.1 Statement Applicable to the Mylan Defendants (hereinafter “Mylan Response”) at 4. Plaintiffs, in paragraph 70(a) to their First Amended Consolidated Complaint (hereinafter “FACC”), named Mylan Laboratories, Inc. as a defendant, alleging that it “engaged in the business of manufacturing and selling pharmaceuticals, mainly through its subsidiaries.” *See* FACC at 25. Mylan, in its Answer and Affirmative Defenses to Plaintiffs’ Revised First Amended Consolidated Complaint (hereinafter “Mylan Answer”), denied the allegation “except admits that Mylan Laboratories Inc is a Pennsylvania corporation whose principal place of business is located at 1500 Corporate Drive, Canonsburg, Pennsylvania, 15317.” Mylan Answer

at 7. The specific Mylan drugs at issue are Clonazepam .5 MG Tablet, Enalapril Maleate 20 MG Tablet, Lorazepam 1MG Tablet, Metoprolol 100 MG Tablet and Ranitidine 150 MG Tablet.

RESPONSE:

Mylan does not dispute Plaintiffs' SOF ¶ 2, except avers that Clonazepam 0.5 MG Tablet, Enalapril Maleate 20 MG Tablet, Lorazepam 1MG Tablet, Metoprolol 100 MG Tablet and Ranitidine 150 MG Tablet were among the nine drugs identified by Plaintiffs and Defendants in this case for targeted FUL-related discovery. Mylan disputes the characterization implicit in the statement "specific Mylan drugs at issue" to the extent it implies that Mylan's reported AWP or WACs for such drugs were actually used or could have been used to set the FUL.

Plaintiffs' Reply to Statement #2:

The parties agree that the drugs at issue are Clonazepam 0.5 MG Tablet, Enalapril Maleate 20 MG Tablet, Lorazepam 1MG Tablet, Metoprolol 100 MG Tablet and Ranitidine 150 MG Tablet.

Mylan cannot reasonably dispute that its reported AWP or WACs for the drugs at issue on this motion were used or could have been used to set the FUL. Mylan reported AWP and WACs to the Compendia, as set forth in plaintiffs' reply to Statements 11-13 herein. Mylan knew CMS set FULs based on the published prices in the Compendia.

Q. All right. And do you know what that stands for, CMS?

A. Center For Medicaid and Medicare Services.

Q. And what does HCFA stand for?

A. Health Care Financing Association or --

Q. Or Administration --

A. -- Administration.

Q. All right. And that's the agency that sets FULs?

A. I believe so, yes.

Q. All right. And how do they go about setting a FUL?

A. In the past there was a formula that they used to calculate a federal upper limit.

Q. And do you know what that formula is or has been?

A. I might not be totally accurate, but it was -- there had to be three products on the market and it was 150 percent of the lowest price.

Q. The lowest published price?

A. I think it was the lowest published price in the compendia.

Krinke 6/11/08 Dep. (Exhibit H) at 34:11-35:7.

Mylan's Knowledge of the Federal Medicaid Rebate Agreement

2. Mylan has entered into and executed the federal Medicaid rebate agreement pursuant to 42 U.S.C. § 1396r-8. *See* Mylan Laboratories, Inc. 30(b)(6) (Brian Roman) (rough copy) dated 11/16/06 (Exhibit B) at 55:18-56:2; Mylan Laboratories, Inc. 30(b)(6) (Brian Roman) (rough copy) dated 7/26/06 ("Mylan 30(b)(6) (Roman) 7/26/06 Dep.") (Exhibit C) at 57:12-58:17. Defendants Mylan Laboratories Inc., Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc.'s Answer and Affirmative Defenses to Plaintiffs' revised First Amended Consolidated Complaint [Docket # 4855] ("Mylan Answer") at ¶¶132.& 168; *Commonwealth of Mass. v. Mylan*, 2008 WL 5650859 (D.Mass) ("Mylan") at *22.

RESPONSE: Mylan does not dispute Plaintiffs' SOF ¶ 3, except avers that Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. have separately entered into rebate agreements with the Department of Health and Human Services and the various states, including the State of New York, pursuant to 42 U.S.C. § 1396r-8. Palermo Decl., Exs. F (rebate agreement entered into between Mylan Pharmaceuticals Inc. and the Secretary of Health and Human Services, dated February 11, 1991 ("MPI Rebate Agreement")) & G (rebate agreement entered into between UDL Laboratories, Inc. and the Secretary of Health and Human Services, dated February 11, 1991 ("UDL Rebate Agreement")). Mylan Inc. has not entered into any rebate agreement. Pursuant to the terms of Mylan Pharmaceuticals Inc.'s and UDL Laboratories, Inc.'s rebate agreements, to which the State of New York State is a party, Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. calculated and reported AMPs and paid rebates on a quarterly basis. *Id.*, Ex. H (Deposition of Mylan's Designee, Brian Roman, dated August 2, 2007 ("Mylan 8/2/07 Dep.)) at 66:09-72:13; Ex. A (Mylan 11/16/06 Dep., at 61:12-62:07.

Plaintiffs' Reply to Statement #3:

Parties agree that Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. have executed the federal Medicaid rebate agreement.

3. Mylan was required as matter of law to familiarize itself with the legal requirements, standards and procedures of the Medicaid program. *Mylan* at *25.

RESPONSE: Mylan disputes Plaintiffs' SOF ¶ 4 to the extent it imposes or seeks to impose on Mylan, either retroactively or prospectively, an obligation to investigate the intricacies and rationale, written or unwritten, behind each State agency's Medicaid reimbursement policy and payments to pharmacies participating in the Medicaid program. At all relevant times, Mylan has complied with the legal requirements, standards or procedures that govern the manner in which drug manufacturers interact

with the various state Medicaid programs, including the New York Medicaid program, and takes its obligations seriously:

Q. Your company is responsible for knowing the rules and regulations of the Medicaid program; is that correct?

A. I -- I'd agree that we're responsible for knowing the rules and regulations that govern the way that we interact with the Medicaid program. There are a lot of aspects of the Medicaid program that we don't participate in, for example, when the Medicaid program pays doctors and things like that. There's -- there are things that we are involved in and many things that we're not. And we are -- we are certainly responsible for and take seriously our obligation to understand, know and comply with the rules that apply to us.

Q. And does your company assume the responsibility of behaving completely honestly and above board in connection with the states' Medicaid programs?

A. Absolutely.

Q. And your company is responsible for knowing the laws that govern the states' Medicaid programs; is that correct?

A. Again, the rules that apply to the way that we interact with the Medicaid programs, I'd agree with that.

Id., Ex. A (Mylan 11/16/06 Dep.) at 61:12-62:7.

Mylan's obligations, duties and responsibilities under the rebate program and Medicaid programs generally, are precisely delineated in Section II of the Medicaid rebate agreement, which includes, *inter alia*, an obligation to make timely rebate payments to each State for drugs covered by Medicaid, calculate and report Average Manufacturer Price ("AMP") on a quarterly basis for each NDC beginning with the first quarter of 1991, calculate and report any prior quarter adjustments to AMP, directly notify the States of a new drug's coverage, to retain records of underlying data used to calculate AMP for a specified period of time, and to comply with the conditions of 42 U.S.C. § 1396 and "changes thereto and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer." Palermo Decl., Ex. F (MPI rebate agreement) § II. Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. have each fully complied with the terms and conditions set forth in their respective rebate agreements, as well any legal requirements, standards and procedures of the Medicaid program applicable to participating drug manufacturers. *Id.*, Ex. H (Mylan 8/2/07 Dep.) at 66:09-72:13; Ex. A (Mylan 11/16/06 Dep.) at 61:12-62:07; Ex. D (Mylan 7/26/06 Dep.) at 57:12-23, 81:15-82:5; Ex. I (Deposition of Robert Cunard dated October 26, 2007 ("Cunard 10/26/07 Dep.)) at 278:09-280:01; Ex. J (Deposition of Harry A. Korman dated March 25, 2009 ("Korman 3/25/09 Dep.") at 157:07-158:12. Neither the rebate agreement nor 42 U.S.C. § 1396 instruct drug manufacturers as to how AWP or WAC should be defined, calculated, or reported to third-party pricing compendia. *See id.*, Ex. F (MPI rebate agreement); 42 U.S.C. § 1396 et seq. The State of New York also does not define or instruct manufacturers in how to calculate and report AWP or WAC. *See*,

e.g., N.Y. Soc. Serv. L. sec 367-a(9)(b). In fact, the only statutory or regulatory definition of WAC is contained in 42 U.S.C. § 1395w-3a, which states as follows:

The term “wholesale acquisition cost” means, with respect to a drug or biological, the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, *not including prompt pay or other discounts, rebates or reductions in price*, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

42 1396 § 1395w-3a (effective December 8, 2003) (emphasis added). There is no evidence that this definition reflected a change in the understanding of WAC, and there is no suggestion that New York or the federal government previously thought WAC meant anything different from or contrary to the federal definition.

The corporate compliance department at Mylan has also ensured Mylan’s compliance with the “[l]aws, regulations, ethics...[Mylan’s] own code of ethics, [and] standards for interactions with health care providers.” Palermo Decl., Ex. D (Mylan 7/26/06 Dep.) at 134:1-4. Mylan also objects to Plaintiffs’ SOF ¶ 4, and specifically Plaintiffs’ citation to the Court’s opinion in *Commonwealth of Massachusetts v. Mylan Laboratories, et al.*, 2008 WL 5650859 (D. Mass. Dec. 23, 2008), insofar as it quotes the Court’s opinion out of context and calls for an improper legal conclusion not supported by the facts in the record.

Plaintiffs’ Reply to Statement #4:

The parties agree with the record evidence cited by Mylan that Mylan is “responsible for knowing the rules and regulations that govern the way that [it] interact[s] with the Medicaid program.” *See* Palermo Decl Ex. A (Mylan 11/16/06 Dep. at 61:12-62:7).

The parties agree further that Mylan has “obligations, duties and responsibilities under the rebate program and Medicaid programs.”

The remainder of Mylan’s response is argument not appropriate in a 56.1. Plaintiffs disagrees, obviously, with Mylan’s assertion that it has complied with the law. No further reply is required.

4. Mylan participates in and is aware of State Medicaid reimbursement formulas, including the New York State Medicaid Program. *See* Exhibit D (Mylan 30(b)(6) (Workman) 9/26/07 Dep. Exhibit 4 (Mylan Medicaid Reimbursement Comparison Worksheet listing Medicaid reimbursements formulas for all states)); *see also* Exhibit E (Cunard 10/26/07 Dep. Exhibit 13; *see* Deposition of Robert Cunard dated 10/30/08 (“Cunard 10/30/08 Dep.”) (Exhibit F) at 92:2-13; *see also* Exhibit G (Cunard 10/26/07 Dep. Exhibit 19 (Mylan August 2001 email string and attachment regarding Ohio State Medicaid formula)); *see* Deposition of Stephen Krinke dated 6/11/08 (“Krinke 6/11/08 Dep.”) (Exhibit H) at 353:12-354:21.

RESPONSE: Mylan disputes Plaintiffs’ SOF ¶ 5. Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. have separately entered into rebate agreements and, pursuant to those respective agreements, have each calculated and reported AMPs and paid rebates on a quarterly basis to the various states for drugs eligible for coverage under the various state Medicaid programs. *Id.*, Ex. H (Mylan 8/2/07 Dep.) at 66:9-72:13; Ex. D (Mylan 7/26/06 Dep.) at 57:12-23; 81:15-82:5. Mylan does not have any involvement in how state Medicaid programs, including the New York State Medicaid Program, determine or apply their state Medicaid reimbursement formulas. *Id.*, Ex. I (Cunard 10/26/07 Dep.) at 125:14-126:17 (Mylan does not “control” or “influence” the “variables that would go into a reimbursement methodology”). It is Mylan’s general understanding that State Medicaid agencies have flexibility in determining how they run their Medicaid programs, which includes designing and implementing their reimbursement payment methodology to ensure access to care and compliance with any other applicable federal statutes and regulations. *Id.*, Ex. D (Mylan 7/26/07 Dep.) at 30:12-31:03. As Mylan’s 30(b)(6) designee, Brian Roman, testified:

Q. Why don’t we do this. Let’s look briefly at Medicaid reimbursement and how it works. Do you have an understanding about how Medicaid reimbursement works?

A. Yeah. My understanding is that it differs from state to state. And with any state, it probably has changed over time. But what you will see is various -- each state designing their own program the way they want to design it to pay -- find a way to pay pharmacies to make sure that the people in their state who are getting Medicaid benefits have access to the medicines that they need. And like I said, every state has their own way of going about doing that, of designing their program in a way that they feel is efficient. And that’s my general understanding of it.

Id., Ex. D (Mylan 7/26/07 Dep.) at 30:12-31:03.

Mylan also disputes the characterization implicit in the statement “aware of State Medicaid reimbursement formulas.” It is not Mylan’s practice or policy to consider State Medicaid reimbursement formulas or payments when setting its prices. *Id.*, Ex. H (Mylan 8/2/07 Dep.) at 194:18-195:15. It is not Mylan’s practice or policy to consider State Medicaid reimbursement formulas or payments when reporting AWP and WAC to

pricing compendia. *Id.*, Ex. K (Deposition of Mylan's Designee, Harry A. Korman, dated November 26, 2007 ("Mylan 11/26/07 Dep.") at 15:15-18:13. It is not Mylan's practice or policy to attempt to "target a Medicaid market" when selling or marketing its products to customers:

Q. What I'm really asking is: Does Mylan make concerted efforts to market its drugs that are reimbursed by Medicaid and take any particular steps to promote or maintain that market?

A. We don't think about a Medicaid market or target a Medicaid market or anything like that. What we do is try to sell our products to our customers at Mylan Pharmaceuticals. Those are principally drug wholesalers and these warehousing retail chains. And we sell based on the competitive environment that we're in where we're trying to get business, and there are other generic companies, often many other generic companies, competing to get that same business. So we're competing on price, and that would be our focus. We are looking for ways to make sure our customers can get our product, that it's not on back order, that we're able to fill their orders, get it to them quickly, get them a high quality product at a price that is competitive. So that's the focus of our sales and marketing, not the back end of reimbursement.

Id., Ex. D (Mylan 7/26/06 Dep.) at 28:12-29:10. As Mr. Krinke, director of trade relations and government affairs at Mylan Pharmaceuticals Inc. during the relevant time period, testified:

Q: Would you agree with me that a manufacturer trying to se[ll] pharmaceuticals to pharmacies, that maximizing the pharmacies' profitability on the product is a good way to try and sell the product?

A. That's not Mylan's focus of selling products to our customers. As I mentioned, we don't know what kind of contracts they sign with third-party payers, so we just try to sell them the product at the price that they can live with and that we are happy with, and what happens after that is their responsibility.

Id., Ex. L (Deposition of Stephen Krinke dated September 25, 2007 ("Krinke 9/25/07 Dep.)) at 238:13 – 239:03. It is not Mylan's general practice or policy to monitor or track how each of the hundreds of different drugs manufactured and sold by Mylan Pharmaceuticals Inc. or UDL Laboratories Inc. were being reimbursed by various state Medicaid agencies. Palermo Decl., Ex. L (Krinke 9/25/07 Dep.) at 193:14–194:07; Ex. B (Korman 11/26/07 Dep.) at 142:02–08. Plaintiffs cite to Exhibit D in alleged support of their contention that Mylan "participates in and is aware of State Medicaid reimbursement formulas, including the New York State Medicaid Program." Plaintiffs' SOF ¶ 5. This document appears to represent nothing more than an isolated comparison between a brand versus generic reimbursement scenario with respect to one (Drug VII or

Nifedipine) out of the hundreds of drugs manufactured and sold by Mylan between 1997 to 2005, and which drug is not at issue in connection with Plaintiffs' present motion. Plaintiffs' SOF, Ex. D. Plaintiffs misleadingly cite to Exhibit E to as further purported evidence of Mylan's alleged "awareness of State Medicaid reimbursement formulas," but which is in fact the same document as Plaintiffs' Exhibit D. Present or former employees at Mylan, including present and former directors of pricing and contracts at Mylan Pharmaceuticals Inc., all testified that they did not have any working knowledge or familiarity with this document and that this type of document would not have been used by Mylan for setting prices or selling any products. *Id.*, Ex. I (Cunard 10/26/07 Dep.) at 225:03-21; Ex. M (Deposition of David Workman dated September 26, 2007 ("Workman 9/26/07 Dep.)) at 169:07-170:15; *see also* Ex. L (Krinke 9/25/07 Dep.) at 215:09-19. Mylan further disputes Plaintiffs' characterization of David Workman's September 26, 2007 deposition as a 30(b)(6) deposition, insofar as Mr. Workman was deposed as an individual fact witness on September 26, 2007.

Plaintiffs' citation to Exhibit G is equally unavailing. Plaintiffs' Exhibit G constitutes one e-mail string (out of several million pages of e-mails and attachments that Mylan has produced to Plaintiffs) reflecting an internal discussion prompted by a question raised by Anthem, an insurance company that also maintains a mail order pharmacy, concerning the reimbursement formula for Ohio Medicaid (and not New York) with respect to one drug (which is also not at issue on this present motion). *See* Plaintiffs' SOF, Ex. G. Plaintiffs have cited no evidentiary basis to support Plaintiffs' SOF ¶ 5.

Plaintiffs' reliance on the deposition testimonies of Mr. Cunard and Mr. Krinke is also improper, as they do not support the statement. Mr. Cunard stated that his knowledge of the Texas Medicaid Program derived from certain publications, such as "Drug Topics." Plaintiffs' SOF, Ex. F. When earlier asked about his use of this publication, Mr. Cunard testified that it was only a source of reference and not consulted on a routine basis, and that it was mainly maintained, if at all, in order to retain copies of Mylan's advertisements that ran in those publications. Palermo Decl., Ex. I (Cunard 10/26/07 Dep.) at 257:8-259:13. In addition, the testimony of Mr. Krinke recited by Plaintiffs from his June 2008 deposition simply discussed the effect of changing an element of a hypothetical reimbursement formula, and does not demonstrate any awareness of any particular reimbursement formula used by any state. Plaintiffs' SOF, Ex. H. None of the incomplete deposition testimony or documents cherry-picked by Plaintiffs from the vast collection of documents and e-mails produced by Mylan in this case lends support to the notion that Mylan monitored or tracked each state's Medicaid reimbursement formula, including New York Medicaid's reimbursement formula and payments to providers.

Plaintiffs' Reply to Statement #5:

Mylan does not dispute that it is aware of the New York State Medicaid reimbursement formula. The cited testimony also demonstrates this. Mr. Cunard testified as follows:

Q: (By Mr. Crawford) All right. Do you have any working knowledge and understanding of how the reimbursement of a Medicaid drug takes place in Texas or any other state?

A: I – I have some knowledge, yes.

Q: Tell me what you know.

A: Most of my information is – comes from what has been published in various trade journals – I think Drug Topics may be one – that on a regular basis publishes what state Medicaid reimbursement rates are as a function of AWP or WAC or MAC and what dispensing fees are, and that is my understanding.

Cunard 10/30/08 Dep. (Exhibit F) at 92:2-13.

Mylan's assertion that the testimony of Mr. Krinke is unreliable because it concerns a hypothetical is without merit. Such hypotheticals demonstrate Mr. Krinke's general knowledge of how State Medicaid reimbursement formulas operate. Mylan cannot reasonably dispute that such knowledge can be ascribed to Mylan. The testimony of Mr. Krinke follows:

Q: (By Ms. Soifer) All right. I'm going to start at Line 2 and I'm going to read the question and then I'm going to ask that you read the answer. The question at Line 2 on Page 49 of the trial in this FTC case, which was on May 10th, 2005, and this is reading from your deposition at that trial.

The question is: "Would AWP reimbursement would it be true that the higher the AWP the higher the reimbursement?"

And what is your answer at Line 3?

A: I'm not sure if I'm – is it right here (indicating)?

Q: Yes.

A: "Answer: No."

Q: Yes. And then the question was – actually, that was at Line 3. The question at Line 5 is, "Why not?"

Will you read your – your answer starting at line 6?

A: "As I mentioned, the AWP is a starting point whereby a percentage is deducted from that percentage."

Q: Keep going.

A: Excuse me. "So depending on the plan and what, how much the deduction is from AWP to get down to a number where they will add the dispensing fee, it would vary."

Q: Does that conclude your answer?

A: Yes.

Q: And the question at Line 11 is, "But if the formula remained the same, then it would be true, though, that the higher the AWP the higher the reimbursement."

And your answer at Line 14 was?

A: "Yes, all things being equal."

Krinke 6/11/08 Dep. (Exhibit H) at 353:12-354:21.

Mylan's dispute regarding Exhibits E and F is baseless. The Exhibits set forth the reimbursement formulas for all states, and reveal Mylan's awareness of state Medicaid reimbursement formulas, including New York's.

Plaintiffs agree that David Workman's September 26, 2007 deposition, contrary to what the reporter indicated on the transcript, was not as a 30(b)(6) deposition

The remainder of Mylan's response is disputed and constitutes argument improper for a 56.1 opposition. Mylan's response also fails to comply with Fed.R.Civ. P. 56.1 in that it is not a "concise statement of material facts of record."

5. Mylan knew that AWP, WAC, and FUL/MAC were used by state Medicaid agencies to determine reimbursement. *See* Exhibit I (Mylan 30(b)(6) (Workman) 9/26/07 Dep. Exhibit 3 (Mylan reimbursement comparison worksheet comparing Mylan generic product to brand product and generic competitor, which identifies the reimbursement percentages relating to AWP and WAC); *See* Cunard 10/30/08 Dep. (Exhibit F) at 92:2-13; Deposition of Robert Cunard dated 10/26/07 ("Cunard 10/26/07 Dep.") (Exhibit J) at 121:2-122:21; Krinke 6/11/08 Dep. (Exhibit H) at 351:1-5 and 423:12-424:1; *see* Mylan 30(b)(6) (Roman) 7/26/06 Dep. (Exhibit C) at 45:15-20; Exhibit K (Krinke 06/11/08 Dep. Exhibit 40 (Email, dated 1/18/02, demonstrating Mylan's knowledge that the State of New York's Medicaid reimbursement formula was AWP minus 10 percent)).

RESPONSE: Mylan disputes Plaintiffs' SOF ¶ 6. Reimbursement payment under each state's Medicaid program, including the New York Medicaid program, can be based on a host of competing factors, including but not limited to the manufacturer's reported price(s), the FUL, the state maximum allowable cost ("MAC") and, more importantly, the usual and customary charge or billed amount ("U&C"), which generally represents in most states the usual and customary charge by the pharmacy for its services to the general public. *Id.*, Ex. N (NYCO-AWPNYDOH- 03883; NYCO-AWP-NYDOH-04346; NYCO-AWP-NYDOH-04324-26); *see also* 42 C.F.R. 512(b)(1). Based on this lower-of payment methodology and the U&C, Mylan lacks visibility into whether the AWP's or WACs reported for its products, including the drugs selected for targeted FUL-related discovery in this case, were in fact being used by New York or other state Medicaid programs to calculate reimbursement payments to providers. *Id.*, Ex. D (Mylan 7/26/07 Dep.) at 172:09-23; Ex. I (Cunard 10/26/07 Dep.) at 125:14-126:17 (Mylan does not "control" or "influence" the "variables that would go into a reimbursement methodology"). Moreover, it is not Mylan's practice or policy to consider reimbursement payments to

providers when setting or reporting AWP or WAC for its products. *Id.*, Ex. K (Mylan 11/26/07 Dep.) at 15:15-18:13; Ex. H (Mylan 8/2/07 Dep.) at 181:03-22.

Plaintiffs cite to Exhibit I in alleged support of its contention that Mylan “knew AWP, WAC, and FUL/MAC were used by state Medicaid agencies to determine reimbursement.” Plaintiffs’ SOF ¶ 6. As explained above, due to the way in which each state’s Medicaid reimbursement methodology is designed, Mylan lacks visibility into how each provider was actually being reimbursed by the New York Medicaid program. *See, e.g.*, N.Y. Soc. Serv. L. § 367-a(9)(b). Moreover, Exhibit I concerns only one drug (Drug VII or Nifedipine, which is the same drug reviewed in connection with Plaintiffs’ Exhibit D, and which is not one of the nine FUL-targeted drugs allegedly at issue on this motion) out of the literally hundreds of drugs manufactured or sold by Mylan. Plaintiffs’ SOF, Ex. I. Mylan further disputes Plaintiffs’ characterization of David Workman’s September 26, 2007 deposition as a 30(b)(6) deposition, insofar as Mr. Workman was deposed as an individual fact witness on September 26, 2007.

Mylan disputes Plaintiffs’ characterization of their Exhibit K as any purported evidence of Mylan’s “knowledge that the State of New York’s Medicaid reimbursement formula was AWP minus 10 percent.” A review of this e-mail chain indicates that it is an impromptu review of New York’s Medicaid reimbursement formula conducted by Stephen Krinke in response to a customer’s inquiry concerning reimbursement by New York Medicaid and Blue Cross Blue Shield. *See* Plaintiffs’ SOF, Ex. K. Plaintiffs also conveniently ignore Mr. Cunard’s admonition expressed within this same e-mail chain that Mylan should not “want to set a precedent by reimbursing [non-warehousing customers] for any margin they lose on the sell side.” *Id.* Mylan does not maintain that none of its employees ever received information relating to Medicaid reimbursement formulas:

A. ... In terms of whether there are people who may get information about reimbursement structures and so on, there probably are people who get that information. But there’s no person whose job is to be a person who is focused on what Medicaid reimbursement is as their sole or even primary duty. There are people in the organization who get information about those things and have some level of awareness of reimbursement issues.

Id., Ex. D (Mylan 7/26/06 Dep.) at 29:22-30:10. However, this by no means demonstrates that Mylan itself monitored, tracked or even had any operational knowledge of each State Medicaid’s reimbursement formulas, including the New York Medicaid program’s reimbursement formula and any changes thereto, or that such information was ever used to set prices or market pharmaceuticals. *Id.*, Ex. H (Mylan 8/2/07 Dep.) at 194:18-195:15; Ex. L (Krinke 9/25/07 Dep.) at 193:14-194:07; Ex. B (Korman 11/26/07 Dep.) at 142:02-8; Ex. A (Mylan 11/16/06 Dep.) at 74:16-75:5 (“we don’t price our drugs based on what the federal upper limits are”).

Plaintiffs' Reply to Statement #6:

Mylan is deliberately misconstruing the Statement in order to confuse the issue. It is entirely unnecessary for Mylan to know the basis upon which every Medicaid claim is paid, or for that matter, the details of New York's reimbursement methodology, in order for the Statement to be both true and undisputed. The cited record evidence speaks for itself:

THE WITNESS: I'm aware that there's different methodologies for third-party reimbursement.

Q. (By Mr. Mullin) And – and some of them are AWP-based, right?

A. Yes.

Q. Some of them are WAC-based?

A. Yes.

...

THE WITNESS: As indicated previously, we develop a proposed AWP that is submitted. And – and, yes, we establish a WAC based on a competitive scene – scenario of the market.

...

Q. (By Mr. Mullin) Can you think of any way that having a higher AWP would not result in a higher reimbursement to a pharmacy for every third-party payer who's AWP-based?

MR. ESCOBAR: Objection to the form.

THE WITNESS: Well, there's many other points that are used in reimbursements, such as MAC and other elements as well. So yes, I could see cases where an AWP is not relevant in the reimbursement.

Cunard 10/26/07 Dep. at 121:14-122:21. *See also* Krinke 6/11/08 Dep. (Exhibit H) at 351:1-5 (“Q. And you agree that in some cases AWP historically has been a starting place for reimbursement, particularly by some state Medicaid programs? A. Yes.”). *See also id.* at 423:12-424:1, stating the following:

Q. How did you come – become familiar with which states had Medicaid reimbursement based on WAC plus a dispensing fee as opposed to which ones reimbursement was an AWP minus scenario?

A. The source was more than likely the Drug Topics chart that's printed every year.

Q. But you felt like the regional managers and directors, and that's of the sales force, right?

A. Yes.

Q. Needed to understand how these reimbursement scenarios worked if there was not a FUL?

A. Well, they may have asked me to help them understand it because they were getting questions and so I probably was trying to help them better understand how it works.

In further response, plaintiffs dispute and object to all citations herein to the Palermo Decl. to the extent that the exhibits cited therein have not been authenticated and otherwise lack proper foundation.

No further reply is required.

6. Mylan knew that the primary purpose for reporting its AWP, was to have its products recognized by databases and by third-party payers, including Medicaid, which reimbursed customers (*see* Mylan Laboratories, Inc. 30(b)(6) (Stephen Krinke) (rough copy) dated 9/25/07 (“Mylan 30(b)(6) (Krinke) 9/25/07 Dep.”) (Exhibit L) at 31:11-32:14, 87:18-88:1).

RESPONSE: Mylan disputes Plaintiffs’ SOF ¶ 7. As Brian Roman, Mylan’s 30(b)(6) designee, explained, Mylan reports the AWP to various pricing compendia, such as First DataBank, in order to “get [Mylan’s] drug classified by First DataBank as a generic drug eligible for substitution.” Palermo Decl., Ex. D (Mylan 7/26/06 Dep.) at 67:02-22; Ex. K (Mylan 11/26/07 Dep.) at 17:15-18:2 (Mylan’s primary purpose for reporting AWP to the pricing compendia was “to make the marketplace aware that the products were being marketed and were available for sale”). Moreover, as Hal Korman, Mylan’s 30(b)(6) designee, testified, reimbursement to providers was not a factor, much less a primary factor, motivating Mylan’s decision to report AWP to pricing compendia:

Q: Was one of Mylan’s purposes in reporting these prices to First Data Bank so that these prices could be used by others for reimbursement purposes?

A: No.

Id., Ex. K (Mylan 11/26/07 Dep.) at 17:15-19; *see* also Ex. H (Mylan 8/2/07 Dep.) at 123:02-05 (Mylan’s primary purpose for reporting AWP to First DataBank was “so that the trades and the industry would know we had a generic version available, and it was being sold at a discount to brand.”) Mylan further disputes Plaintiffs’ characterization of Stephen Krinke’s September 25, 2007 deposition as a 30(b)(6) deposition, insofar as Mr. Krinke was deposed as an individual fact witness on September 25, 2007.

Plaintiffs' Reply to Statement #7:

Mylan admits that it reported AWP's to the pricing Compendia at least in part to let the market know Mylan's drugs were being marketed and available for sale. Beyond that, the record evidence speaks for itself:

Q. Can you describe for me what those government affairs responsibilities were?

A. To ensure that Mylan products were approved for reimbursement by third-party entities.

Q. Can you explain to me what you mean by that?

A. I would ensure that the – that Mylan products were available to a pharmacist to dispense on a prescription and be reimbursed for them.

Q. By government, by third parties, by whom?

A. I don't understand the question.

Q. I think you said that one of your responsibilities was to make sure that Mylan products were eligible to be reimbursed, right?

A. Yes.

Q. And was that to be reimbursed by government programs?

A. Possibly.

Q. Okay.

And also independent, third-party payers like health insurance plans and people like that?

A. Yes.

Krinke 9/25/07 Dep. (rough copy) (Exhibit L) at 31:11-32:14. *See also id.* at 87:11-88:1, stating the following:

COURT REPORTER: "Question: Is it fair – is it accurate to say that the primary purpose for reporting AWP prices to these national databases is for reimbursement purposes?"

MR. ESCOBAR: Same objection.

BY MR. MULLIN:

Q. You may answer.

A. The primary purpose is to report to the databases so that your product is recognized not only by the database, but by customers and third parties that may use that information to determine whether they will reimburse for your product.

Plaintiffs agree that Stephen Krinke's September 25, 2007 deposition was in the capacity of an individual and not as a 30(b)(6) witness as mistakenly indicated by the court reporter on the transcript.

7. Mylan knew that the majority of brand and generic prescriptions were covered by third-party reimbursement (*see* Mylan 30(b)(6) (Krinke) 9/25/07 Dep. (Exhibit L) at 307:3-308:14; *see also* Exhibit M (Mylan 30(b)(6) (Krinke) 9/25/07 Dep. Exhibit 12).

RESPONSE: Mylan disputes Plaintiffs' SOF ¶ 8. Plaintiffs' SOF ¶ 8 is not supported by the document cited and mischaracterizes the testimony of Stephen Krinke. Mylan receives Medicaid rebate invoices from the states on a quarterly basis but does not keep track of the percentage of its total sales that are attributable to Medicaid. *Id.*, Ex. D (Mylan 7/26/06 Dep.) at 26:14-27:10; *see also* Ex. H (Mylan 8/2/07 Dep.) at 194:02-15. None of the Mylan witnesses deposed to date have testified that they were aware that "the majority of brand and generic" drugs sold by Mylan (or other manufacturers generally) were "covered by third-party reimbursement." Indeed, when Mylan's 30(b)(6) witness, Brian Roman, in preparation for his 30(b)(6) deposition asked Mr. Krinke whether the "Medicaid program was a major source of reimbursement for pharmaceuticals," Mr. Krinke only recalled reading in a trade press "some figures like ten or eleven percent on an industry wide basis." *Id.*, Ex. H (Mylan 8/2/07 Dep.) at 194:02-17 (emphasis added).

Plaintiffs' Exhibit M to the September 25, 2007 deposition of Stephen Krinke appears to be a 2-page spreadsheet depicting the WACs and FULs associated with several products manufactured and sold by Mylan and Watson (out of the hundreds of products sold by Mylan that do not appear on this list). When specifically questioned about this document, Mr. Krinke testified that he had "no idea" what percentage of sales were attributable to Medicaid and was unable to explain the source, significance or accuracy of the figures reported on the spreadsheet. *Id.*, Ex. L (Krinke 9/25/07 Dep.) at 193:14-194:07; Plaintiffs' SOF, Ex. L, at 307:3-308:14. Mylan's 30(b)(6) designee, Brian Roman, further testified that Mylan does not track the percentage of its sales ultimately reimbursed by Medicaid. *Id.*, Ex. H (Mylan 8/2/07 Dep.) at 193:1-194:1; *see also* Ex. D (Mylan 7/26/06 Dep.) at 28:12-29:10. Mylan further disputes Plaintiffs' characterization of Stephen Krinke's September 25, 2007 deposition as a 30(b)(6) deposition, insofar as Mr. Krinke was deposed as an individual fact witness on September 25, 2007.

Plaintiffs' Reply to Statement #8:

The parties agree that some portion of Mylan's drugs are reimbursed by Medicaid. The parties agree that Mylan's corporate designee testified that something like 10-11% of sales are reimbursed by Medicaid on an industry-wide basis. No further reply is required.

Mylan Set and Reported Its AWP's and WACs

8. For each of its generic drugs, Mylan generally set the AWP, which it reported to third-party databases, at about 10% to 11% below the corresponding brand AWP. *See* Mylan

30(b)(6) (Krinke) 9/25/07 Dep. (Exhibit L) at 69:21-70:3; Mylan Laboratories, Inc. 30(b)(6) (Brian Roman) (rough copy) dated 8/2/07 (“Mylan 30(b)(6) (Roman) 8/2/07 Dep.”) (Exhibit N) at 142:8-13; *See* Cunard 10/26/07 Dep. (Exhibit J) at 74:18-75:2. If there was generic competition for the product, then Mylan’s AWP may be set at 11% off the brand AWP. *See* Mylan 30(b)(6) (Roman) 8/2/07 Dep. (Exhibit N) at 142:14-19.

RESPONSE: Mylan disputes the first sentence of Plaintiffs’ SOF ¶ 9. Mylan’s AWP is generally a price that is set at the time of launch in reference to the equivalent brand product’s AWP and any generic products’ AWP’s where available. *Id.*, Ex. D (Mylan 7/26/06 Dep.) at 67:2-67:22; Ex. O (Deposition of David Workman dated July 26, 2008 (“Workman 6/26/08 Dep.”)) at 130:16-132:18; Ex. H (Mylan 8/2/07 Dep.) at 138:8-140:21; Ex. I (Cunard 10/26/2007 Dep.) at 64:8-16, 92:16-93:4. Mylan reports the AWP to various pricing compendia, such as First DataBank, in order to “get [Mylan’s] drug classified by First DataBank as a generic drug eligible for substitution.” *Id.*, Ex. D (Mylan 7/26/06 Dep.) at 67:02-22; Ex. K (Mylan 11/26/07 Dep.) at 17:20-18:2. The AWP “doesn’t mean it’s not a price at which our products are sold downstream.” *Id.*, Ex. D (Mylan 7/26/06 Dep.) at 50:06-20.

Mylan disputes the second sentence of Plaintiffs’ SOF ¶ 9. In instances where there are competing generics already in the marketplace, Mylan’s policy is to set its AWP in line with other generic competitors’ AWP’s, and not necessarily higher or lower. *Id.*, Ex. O (Mylan 6/26/08 Dep.) at 131:04-15; Ex. I (Cunard 10/26/2007 Dep.) at 64:8-16; Ex. H (Mylan 8/2/07 Dep.) at 139:5-140:21; Ex. M (Workman 9/26/07 Dep.) at 79:17-80:9. It is not Mylan’s practice or policy to set its AWP at the very minimum discount off brand AWP needed to ensure generic designation by pricing compendia. *Id.*, Ex. H (Mylan 8/2/07 Dep.) at 145:15-22. Indeed, it is not Mylan’s policy to set the highest AWP possible in relation to the brand, as it may create the undesirable “perception [that Mylan’s] product is more expensive” to a potential customer. *Id.*, Ex. O (Mylan 6/26/08 Dep.) at 131:04-132:18.

Mylan further disputes Plaintiffs’ SOF ¶ 9 because it is not supported by the testimony cited. Mr. Krinke simply explained in his testimony that the general understanding in the industry was that for First DataBank to treat a pharmaceutical product as a generic, the AWP “would need to be at least 10 percent below the brand.” *Id.*, Ex. L (Krinke 9/25/07 Dep.) at 71:3-14. Mr. Krinke also testified that “First DataBank...has a formula unbeknownst to the manufacturers that takes into account many things, including the number of competitors and their prices and the brand.” *Id.*, Ex. L (Krinke 9/25/07 Dep.) at 71:3-14; *see also* Ex. H (Mylan 8/2/07 Dep.) at 143:3-144:1. Mylan further disputes Plaintiffs’ characterization of Stephen Krinke’s September 25, 2007 deposition as a 30(b)(6) deposition, insofar as Mr. Krinke was deposed as an individual fact witness on September 25, 2007.

Plaintiffs’ Reply to Statement #9:

The parties agree that Mylan reported on AWP for its drugs to the pricing Compendia.

The parties agree that when there were competing generics in market it was Mylan's policy to set its AWP in line with other generic competitors. The parties agree that at the time of launch Mylan set its AWP in reference to the equivalent brand product's AWP and any generic products. No further reply is required.

9. Mylan set its WAC for products in competitive markets based on the existing competitive conditions. Where there was other generic competition for Mylan drugs, Mylan set WAC by comparing its price to that of its competitors. *See* Mylan 30(b)(6) (Roman) 8/2/07 Dep. (Exhibit N) at 174:14-175:9.

RESPONSE: Mylan does not dispute the first sentence of Plaintiffs' SOF ¶ 10, except avers that Mylan's WAC is the invoice price to wholesalers and represents the price that is being charged to its wholesale customers at the time of sale. *Id.*, Ex. P (Deposition of David Workman dated October 15, 2008 ("Workman 10/15/08 Dep.") at 103:03-24; Ex. A (Mylan 11/16/06 Dep.) at 230:20-233:16; Ex. H (Mylan 8/2/07 Dep.) at 175:15-21, 181:09-182:11. Mylan's WAC is set on a product-by-product basis in light of existing market conditions and the competitive environment. *Id.*, Ex. M (Workman 9/26/07 Dep.) at 98:02-101:13; *see* Ex. I (Cunard 10/26/2007 Dep.) at 64:8-16, 92:16-93:4. To the extent Mylan has negotiated contract prices with retail or indirect customers at the time of launch, Mylan would consider such prices in relation to Mylan's potential chargeback obligations, prompt pay discounts, as well as the manufacturer cost (material-labor-overhead or "MLO") for the product when setting the WAC. *Id.*, Ex. M (Workman 9/26/07 Dep.) at 98:02-104:13; Ex. H (Mylan 8/2/07 Dep.) at 182:01-11.

Mylan's WAC is a real transaction price in the marketplace at the point of sale, as it represents the price that the wholesaler is ultimately responsible for paying:

A. WAC is a real price, and wholesalers, their net prices were based upon that WAC price, but, over time, it evolved where they established their own contract and their own contract price, and that was for their source program, not their entire book of business.

Id., Ex. P (Workman 10/15/08 Dep.) at 107:09-15. Mylan does not know at the point of sale which of the products shipped to the wholesaler at WAC is ultimately resold by the wholesaler or distributor to entities that have an indirect supply contract with Mylan or to entities that have a contract with the wholesaler under the wholesaler's own source program, such that Mylan's chargeback obligations would begin to accrue. *Id.*, Ex. P (Workman 10/15/08 Dep.) at 118:24-119:08 (a wholesaler may "be responsible for the full WAC, because we would not be receiving a chargeback either for a third party or for their source program.") With respect to sales outside the wholesaler source program or entities without a pre-existing contract with Mylan, Mylan's WAC is the price that

wholesale customers pay Mylan with respect to those sales, less any conditional discounts such as the 2% prompt pay or a full-line credit:

A. When they do sell a product out under their source program or under a third-party contract, at a designated negotiated contract price, a chargeback is processed, and a chargeback is the difference between WAC and that contract price. If they sell it to a pharmacy that is not a part of a third-party contract or not a part of their source program, we would not receive a chargeback for that, so they would be responsible for that invoice.

Id., Ex. P (Workman 10/15/08 Dep.) at 106:18-107:3. The WAC is “not an average” but a price that is actually paid by wholesalers and thus “a price point that is representative of the wholesale acquisition cost.” *See also id.*, Ex. P (Workman 10/15/08 Dep.) at 103:13-104:10. Even in the context of sales to indirect customers, WAC represents a price with discernible economic impact since from “a financial perspective, we were concerned of our WAC prices and our prompt payment obligation and our chargeback obligation, compared to our contract prices” and thus Mylan will “analyze all of those components of price when making a [WAC] recommendation.” *Id.*, Ex. M (Workman 9/26/07 Dep.) at 101:20-102:15. In such instances, Mylan’s WAC has real economic implications because it is directly tied to the amount Mylan must pay in discounts, rebates and chargebacks. *Id.*, Ex. D (Mylan 7/26/06 Dep.) at 69:2-70:16; Ex. I (Cunard 10/26/07 Dep.) at 275:03-277:03 (an “increase of WAC where there’s specific discounts tied to it around the wholesale programs would actually be counter-productive to the profitability of Mylan”). As set forth above, Mylan’s WAC is consistent with the federal definition of WAC set forth in 42 U.S.C. § 1395w-3a, which states as follows:

The term “wholesale acquisition cost” means, with respect to a drug or biological, the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

42 1396 § 1395w-3a (effective December 8, 2003).

Mylan disputes the second sentence of Plaintiff’s SOF ¶ 10, insofar as Mylan does not set its WAC solely in reference to its competitors’ WACs. *Id.*, Ex. M (Workman 9/26/07 Dep.) at 98:02-99:04 (when making WAC recommendations, Mr. Workman considered “[m]arket conditions and the competitive environment,” “where we have negotiated contract prices, if they existed,” “where our chargeback obligations were,” and “what our prompt pay value were, as it pertained to not only contract prices but the cost of the product”). As Mr. Workman explained, Mylan may also look at competitors’ other price points obtained through IMS material, wholesaler price lists that are publicly available, federal supply schedule (“FSS”) and/or VA prices available from the US

Department of Veterans Affairs website. *Id.*, Ex. O (Workman 6/26/08 Dep.) at 62:06-63:08, 68:18-70:09.

Plaintiffs also mischaracterize the testimony of Mylan's 30(b)(6) designee, Brian Roman, who in fact testified that it is Mylan's practice to determine a WAC price "based on the existing competitive conditions and the forecast of how the market would shape up." Plaintiffs' SOF, Ex. N.

Plaintiffs' Reply to Statement #10:

Parties agree that Mylan set its WAC for products in competitive markets based on the existing competitive conditions. The remainder of Mylan's response is disputed and constitutes argument improper for a 56.1 opposition. No further reply is required.

10. During the period 1997 to 2005, Mylan communicated AWP for its products to the publishing compendia, which published them. *See* Mylan 30(b)(6) (Roman) 7/26/07 Dep. (Exhibit C) at 48:19-49:02; *see also* Cunard 10/26/2007 Dep. (Exhibit J) at 57:20-59:21; *see also* Mylan, 2008 WL 5650859 at *8.

RESPONSE: Mylan disputes Plaintiffs' SOF ¶ 11 and avers the AWP published by third party pricing compendia, such as First DataBank, may not necessarily reflect the AWP reported by Mylan. Palermo Decl., Ex. C (Mylan 6/26/08 Dep.) at 21:08-22:06; *see also* Ex. D (Mylan 7/26/06 Dep.) at 68:6-19 ("the number we send to First DataBank isn't necessarily the number that they will ultimately publish as the AWP ... they may end up publishing an AWP that is a different number than what we sent in.").

Plaintiffs' Reply to Statement #11:

Mylan cannot reasonably dispute that this Court found that "Mylan reported AWP and WAC to FDB throughout the relevant time period. *Mylan* 608 F. Supp. 2d at 137.

Mylan admits in response to Statements # 1, # 12, and # 20, that it reported AWP to the publishing Compendia. The cited record evidence also supports the proposition. "Mylan communicates an AWP number for its products to a company like First Data Bank." *See* Mylan 30(b)(6) (Roman) 7/26/07 (Exhibit C) at 48:21-49:02.

Any possibility that the publishing compendia might publish an AWP for Mylan which varies in some degree from the AWP reported to it by Mylan, in the absence of evidence that this actually occurred and was not corrected when brought to the compendia's attention by Mylan, is merely improper, speculative argument. This is irrelevant and disputed, as is the remainder of Mylan's response. No further reply is required.

11. Mylan reported its AWP to Red Book, Medi-Span, and FDB. *See* Exhibit O (Mylan 30(b)(6) (Workman) 9/26/07 Dep. Exhibit 9 (Mylan memo, dated 1/13/98, explaining that every AWP is reported to FDB, Medi-Span, Red Book, and HCFA)); Exhibit P (Floyd 12/3/08 Dep. Exhibit 12 (Mylan AWP price change notification, dated 5/21/99, sent to the compendia)); Exhibit Q (Floyd 12/3/08 Dep. Exhibit 18 (Mylan memo, dated 6/21/99, notifying FDB, Medi-Span, and Red Book of changes to its AWP.)).

RESPONSE: Mylan does not dispute Plaintiffs' SOF ¶ 12, except avers that Plaintiffs' SOF ¶ 12 is not supported by Plaintiffs' Exhibit Q. Plaintiffs' Exhibit Q is an internal e-mail to Mylan employees announcing the intention to send notifications of new WACs, but with no indication as to the recipients of those notifications. Plaintiffs' SOF, Ex. Q. Mylan objects to Plaintiffs' citation to Exhibit Q, which does not relate to any of the drugs at issue, contains no reference at all to Medi-Span or Red Book, and reflects only a handwritten notation regarding First DataBank. Plaintiffs' SOF, Ex. Q. Mylan further disputes Plaintiffs' characterization of David Workman's September 26, 2007 deposition as a 30(b)(6) deposition, insofar as Mr. Workman was deposed as an individual fact witness on September 26, 2007.

Plaintiffs' Reply to Statement #12:

The parties agree that Mylan reported its AWP to Red Book, Medi-Span, and FDB. No further reply is required.

12. During the period 1997 to 2005, Mylan reported or caused to be reported WACs for its drugs to FDB. *See* Mylan 30(b)(6) (Roman) 7/26/07 Dep. (Exhibit C) at 49:03-13; *see* Exhibit Q (Floyd 12/3/08 Dep. Exhibit 18 (Mylan email, dated 11/13/98, discussing changes in Mylan AWP and WACs, including a handwritten note that FDB will be informed of those changes); *see also* Mylan, 2008 WL 5650859 at *8.

RESPONSE: Mylan disputes Plaintiffs’ SOF ¶ 13, except avers that Mylan reports WACs to various pricing compendia, including First DataBank. Mylan has not “caused to be reported” WACs, but rather has reported its WACs to third party pricing compendia, including First DataBank, RedBook and Medi-Span. Palermo Decl., Ex. C (Mylan 6/26/08 Dep.) at 28:19-29:02. The WACs published by third party pricing compendia, such as First DataBank, may not necessarily reflect the WACs reported by Mylan. *Id.* Ex. C (Mylan 6/26/08 Dep.) at 21:08-22:06; *see also* Ex. D (Mylan 7/26/06 Dep.) at 104:19-23, 108:12-16 (“there are times when the number that gets published by these publishers isn’t the same as the number that we sent them.”)

Plaintiffs’ Reply to Statement #13:

The parties agree that during relevant period Mylan reported WACs to third-party pricing compendia, including First DataBank, Redbook and Medi-Span. No further reply is required.

Mylan’s Knowledge of the Federal Upper Limits

13. Mylan knew that the FUL was a reimbursement limit established by HCFA/CMS *See* Mylan 30(b)(6) (Krinke) 9/25/07 Dep. (Exhibit L) at 194:12-20; *see also* Mylan 30(b)(6) (Roman) 7/26/07 Dep. (Exhibit C) at 45:15-20. Mylan knew that the FUL calculation was based on a review of the compendia’s published prices, be they AWP or WAC, where at least three competing brand or generic products were at market, and the FUL would be calculated at 150 percent of the lowest published price. *See* Mylan 30(b)(6) (Krinke) 9/25/07 Dep. (Exhibit L) at 194:22-195:20; *see also* Mylan 30(b)(6) (Roman) 7/26/07 Dep. (Exhibit C) at 172:16-173:1.

RESPONSE: Mylan does not dispute the first sentence of Plaintiffs’ SOF ¶ 14, except avers that Mylan has not monitored or kept track of the various FULs that may apply to each of the hundreds of drugs manufactured and sold by Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. *Id.*, Ex. H (Mylan 8/2/07 Dep.) at 194:18-195:15; Ex. B (Korman 11/26/07 Dep.) at 142:02-8; Ex. A (Mylan 11/16/06 Dep.) at 74:16-75:5 (“we don’t price our drugs based on what the federal upper limits are”). Brian Roman, testifying as Mylan’s 30(b)(6) designee, further stated:

A. My understanding is that the federal upper limits are established by the federal centers for Medicare services and are communicated across to all states in some way, shape or form and that those are a cap nationally on what Medicaid programs can pay for generic drugs subject to an FUL.

Id., Ex. D (Mylan 7/26/06 Dep.) at 45:12-20; Ex. A (Mylan 11/16/06 Dep.) at 74:16-75:5 (“we don’t price our drugs based on what the federal upper limits are”).

Mylan disputes the second sentence of Plaintiffs' SOF ¶ 14 and specifically the implicit characterization in the statement "the FUL would be calculated at 150 percent of the lowest published price" as misleading. As a former CMS employee involved in the setting of FULs deposed in this case testified, CMS in many cases intentionally chose not to base FUL on the lowest published price because of concerns that the lowest price would result in an unreasonably low FUL and that this would create issues with access. *Id.*, Ex. E (Gaston Dep.) at 440:18-457:19. Ms. Gaston testified that as part of the manual review performed by CMS prior to setting FUL, CMS elected not to base FUL on the lowest published price for at least three of the Mylan drugs at issue (metoprolol 100 MG, lorazepam 1 MG tablet and clonazepam 0.5 MG tablet), "because setting the FUL on the lowest published price here might not allow us to have a reasonable FUL price for this drug." *Id.*, Ex. E (Gaston Dep.) at 440:18-445:13, 446:1-453:1; *see also* Exs. Q, R & S (printouts from CMS's FUL system showing that the FUL calculated by the computer program was subsequently adjusted upwards for lorazepam, clonazepam and metoprolol as a result of CMS's manual review process).

Plaintiffs' citation to the September 25, 2007 deposition of Mr. Krinke does not support its contention that Mylan knew how CMS calculated the FUL that may be applicable to certain of Mylan's products. Mr. Krinke simply testified that he did not "see how the Federal Upper Limit could limit the reimbursement of Mylan's products" and could not think of an occasion where he discussed the impact of FUL on Mylan's sales of its drugs. *Id.*, Ex. L (Krinke 9/25/07 Dep.) at 196:04-21. Plaintiffs' citation to Brian Roman's testimony is equally unavailing, as Mr. Roman's testimony merely reiterates Mylan's understanding that the states "have a lot of latitude to design [Medicaid] programs" and that state Medicaid programs will be "subject to the FUL if its there." Plaintiffs' SOF, Ex. C. Mylan further disputes Plaintiffs' characterization of Stephen Krinke's September 25, 2007 deposition as a 30(b)(6) deposition, insofar as Mr. Krinke was deposed as an individual fact witness on September 25, 2007.

Plaintiffs' Reply to Statement #14:

The parties agree that Mylan knew that the FUL was a reimbursement limit established by HCFA/CMS. The parties agree that Mylan's 30(b)(6) designee testified that State Medicaid programs will be "subject to FUL if its there." No further reply is required.

14. Mylan monitored its competitors' WACs along with the established FUL level in order to set Mylan prices to be both consistent with its competitors' WACs and also maximize third-party reimbursement to customers. *See* Mylan Laboratories, Inc. 30(b)(6) (David Workman) (rough copy) dated 9/26/07 (Exhibit R) at 213:10-215:7; Exhibit S (Mylan 30(b)(6) (Workman) 9/26/07 Dep. Exhibit 10 (Mylan spreadsheet, dated 8/25/98, comparing Mylan WAC to that of Watson along with the FUL and an analysis of lost Medicaid reimbursement)); *see also*

Exhibit T (Cunard 10/30/08 Dep. Exhibit 15 (Mylan email to Wal-Mart, dated 3/16/01, communicating its efforts to increase customer reimbursement)).

RESPONSE: Mylan disputes Plaintiffs' SOF ¶ 15. As explained above, at all times during the relevant time period, Mylan's WAC was set on a product-by-product basis in light of existing market conditions and the competitive environment. *See supra*, Mylan's response to ¶ 10. Mylan's WAC is the invoice price for "all of [Mylan's] transactions with wholesalers," which comprises "a large part of Mylan Pharmaceuticals' business." *Id.*, Ex. H (Mylan 8/2/07 Dep.) at 175:10-21; Ex. I (Cunard 10/26/07 Dep.) at 94:08-17 ("WAC is the invoice price and the price that wholesalers and distributors pay for the product"). Much like any other business operating in a competitive industry, Mylan has looked at market intelligence and market forecasts as well as its own operating costs, in determining its prices such as the WAC. *Id.*, Ex. H (Mylan 8/2/07 Dep.) at 300:9-301:12; Ex. J (Korman 3/25/09 Dep.) at 153:21-154:11. Within the bounds of the law, Mylan has also obtained pricing information directly from customers, which may also factor into Mylan's setting of its WAC. *Id.*, Ex. D (Mylan 7/26/06 Dep.) at 139:2-20 ("if a customer wants to tell us that they're buying a drug for a particular price, that could be a good source of information"). As part of this determination, Mylan has also looked at its competitors' WACs to gauge its competitors' price points for their products. *Id.*, Ex. O (Mylan 6/26/08 Dep.) at 70:03-09 (describing competitors' WAC as "part of the market information" that Mylan would consult when setting its WAC). As Mr. Workman explained, Mylan may also look at competitors' other price points obtained through IMS material, wholesaler price lists that are publicly available, federal supply schedule ("FSS") and/or VA prices available from the US Department of Veterans Affairs website. *Id.*, Ex. O (Mylan 6/26/08 Dep.) at 62:06-63:08; 68:18-70:09. On the other hand, Mylan has competed on price by charging its customers prices that are *lower than* its competitors' prices, including the WAC:

Q. And when you say the competitive conditions, what do you mean?

A. The factors of supply and demand, looking at who else is selling it, what prices exist in the marketplace; we're never – even though we may be the first generic, that there is an existing marketplace for this drug that has been created by the brand company that exists when we come into it; so, you know, a significant part of the philosophy, as I said, would be that we're offering all of our products as a discount to the brand as an alternative, as a lower price alternative for the same medicine; so the prices would be lower than the corresponding brand prices.

Id., Ex. H (Mylan 8/2/07 Dep.) at 300:9-301:12; *see also* Ex. M (Workman 9/26/07 Dep.) at 98:02-101:13; Ex. I (Cunard 10/26/07 Dep.) at 92:16-93:4; 275:03-277:03 ("[a]djustments to WAC that were done proactively would be more around a decrease because that would decrease our costs to the customer base and increase our profitability if we were able to achieve that"); Ex. L (Krinke 9/25/07 Dep.) at 238:13-239:03 ("we just try to sell them the product at the price that they can live with and that we are happy with, and what happens after that is their responsibility"). To the extent Mylan has negotiated

indirect contract prices at the time of launch, Mylan would consider such prices in relation to Mylan's potential chargeback obligations, prompt pay discounts, as well as the manufacturer cost (material-labor-overhead) for the product, as part of its overall determination of the WAC. *Id.*, Ex. M (Workman 9/26/07 Dep.) at 98:02-104:13; Ex. H (Mylan 8/2/07 Dep.) at 182:01-11.

As demonstrated above, when setting its prices, Mylan has not monitored or tracked how each of the hundreds of different drugs manufactured and sold by Mylan Pharmaceuticals Inc. or UDL Laboratories Inc. were being reimbursed by various state Medicaid agencies. Palermo Decl., Ex. L (Krinke 9/25/07 Dep.) at 193:14-194:07; Ex. B (Korman 11/26/07 Dep.) at 142:02-08. Mylan has not monitored or kept track of the various FULs that may apply to each of the hundreds of drugs manufactured and sold by Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. and how that may impact reimbursement to providers. *Id.*, Ex. H (Mylan 8/2/07 Dep.) at 194:18-195:15 (Mylan "did not make a concerted or regular effort to keep track of the changing methodologies for Medicaid reimbursement"); Ex. L (Krinke 9/25/07 Dep.) at 195:21-196:21 (testifying that "he could not see how Federal Upper Limit could limit reimbursement of Mylan's products" and that he "could not think of an occasion" when he had discussed FULs with anyone at Mylan); Ex. T (Deposition of Robert Cunard dated October 30, 2008 ("Cunard 10/30/08 Dep.")), at 218:10-16 ("I didn't know and – and don't know today what the – what the methodology is for setting FULs"). As Robert Cunard, former VP of marketing at Mylan Pharmaceuticals Inc. further testified, the notion that there was a policy at Mylan to maximize reimbursement payments to pharmacies is "fundamentally flawed." *Id.*, Ex. I (Cunard 10/26/07 Dep.) at 119:08-120:03. Plaintiffs' contention that Mylan manipulated the WACs for drugs with established FULs in order to "maximize third-party reimbursement to customers" is plain wrong and not supported by the documents or testimony cited by Plaintiffs. Plaintiffs' Exhibit A, which allegedly reflects the WACs published by First DataBank and the FULs set by CMS for select Mylan drugs, demonstrates that Mylan did not increase or set its WAC up to the level of the existing FUL in order to ensure that third-party reimbursements were maximized for drugs with applicable FUL. *See* Plaintiffs' SOF, Ex. A. For example, according to Plaintiffs' Exhibit A, while the FUL for ranitidine (00378-3252-05) remained at \$295.70 in 1998, Mylan appears to have decreased its WAC from \$172.50 to \$110.00 (rather than increase the WAC up to the FUL value of \$295.70). *Id.* Similarly, whereas the FUL for metoprolol (00378-0047-01) remained the same at \$11.61 in 1998, Mylan appears to have decreased the WAC from \$15.60 to \$7.25 (rather than setting it to the FUL value of \$11.61 at the time). *Id.* Plaintiffs' Exhibit A corroborates Mr. Workman's testimony that the FUL did not factor into Mylan's pricing decisions:

Q. If one of Mylan's generic products which had been subject to a FUL had – was then no longer subject to a FUL, all right, what are the consequences of that for Mylan and its pricing, if any?

A. I don't believe that it would be a consequence to Mylan.

Palermo Decl., Ex. P (Workman 10/15/08 Dep.) at 164:16-23; Ex. A (Mylan 11/16/06 Dep.) at 74:16-75:5 (“we don’t price our drugs based on what the federal upper limits are”).

Plaintiffs’ citation to Exhibit S (which is the same document as Plaintiffs’ Exhibit M), is misleading and does not support its contention. *See* Plaintiffs’ SOF, Exs. S, M. The document appears to be a single spreadsheet listing Mylan’s WAC, competitor’s WAC and the FUL as of September 1, 1998. When specifically questioned about this document, Mr. Workman testified that he did not “know the specific purpose” of this spreadsheet. Palermo Decl., Ex. M (Workman 9/26/07 Dep.) at 213:10-18. Plaintiffs’ Exhibit A also demonstrates that this spreadsheet, or the information contained therein, had no impact on Mylan’s pricing of WAC, as a cursory review of the WAC associated with Mylan’s metoprolol (00378-0047-01), which appears on Plaintiffs’ Exhibit S and which remained the same throughout this period according to Plaintiffs’ Exhibit A, would demonstrate. *See* Plaintiffs’ SOF, Exs. A & S.

Similarly, Plaintiffs’ citation to Exhibit T is inapposite. When questioned about this document, Robert Cunard testified that the email and the attached spreadsheet, if anything, appeared to be nothing more than his personal reply to a customer’s request for data relating to the WAC and FUL for certain drugs. Palermo Decl., Ex. T (Cunard 10/30/08 Dep.) at 220:02-08 (“at this time nor now do I know how an FUL is created or what goes into it”). There is no evidence in this e-mail or in Mr. Cunard’s deposition testimony that this information was ever used to set the WAC or that Mylan made “efforts to increase customer reimbursement.” *See* Plaintiffs’ SOF, Ex. T; Palermo Decl., Ex. T (Cunard 10/30/08 Dep.) at 217:1-7 (“I believe this was responding to some request that [the customer] made” and “once again...it’s a reporting of...just published pricing”). Moreover, none of the drugs listed on this spreadsheet are drugs selected for FUL-related discovery. *Id.* Mylan further disputes Plaintiffs’ characterization of David Workman’s September 26, 2007 deposition as a 30(b)(6) deposition, insofar as Mr. Workman was deposed as an individual fact witness on September 26, 2007.

Plaintiffs’ Reply to Statement #15:

The parties agree in statements 1, 13, and 20 that Mylan set its WACs. The remainder of Mylan’s response is disputed and constitutes argument improper in a 56.1 opposition. No further reply is required.

15. Mylan knew, at various times, of the prices at which certain of their products were sold to providers and were aware, at various times, that FULs applied to certain of its products generic drugs. Mylan Answer at ¶150.

RESPONSE: Mylan disputes Plaintiffs' SOF ¶ 16, except avers that at various times, Mylan knew the contract prices that Mylan negotiated with and entered into with certain of its customers, including certain large warehousing chains, and was aware that "FULs applied to certain generic products." Mylan's Answer and Affirmative Defenses to Plaintiffs' Revised First Amended Complaint ("Mylan's Answer"), at ¶ 150; *see also* Palermo Decl., Ex. D (Mylan 7/26/06 Dep.) at 52:18-53:11 ("I do know that in terms of generic drugs, in most if not all cases there would likely be a federal upper limit that would actually determine the maximum amount that the Medicaid program could legally reimburse for those products"). Mylan further disputes Plaintiffs' SOF ¶ 16 to the extent it purports to suggest that Mylan knew what every provider, regardless of whether it is an indirect customer of Mylan, was paying for Mylan's products. Palermo Decl., Ex. D (Mylan 7/26/06 Dep.), at 50:6-19.

As stated in its answer, Mylan also denies the allegation in ¶ 150 of Plaintiffs' Revised First Amended Consolidated Complaint that Mylan was ever "aware of the reimbursement prices reported by their competitors, the actual price of their generic competitors' products, their own sales prices to Medicaid providers, and the FUL," and the allegation that Mylan Pharmaceuticals Inc. and/or UDL Laboratories, Inc. "manipulate their own reported reimbursement prices in order to gain or maintain a competitive advantage in the market for their generic products." *See* Mylan's Answer, ¶ 150; *see also* Plaintiffs' Revised First Amended Complaint, served on October 4, 2007, ¶ 150. It is not and has not been Mylan's practice or policy to consider State Medicaid reimbursement formulas or payments when setting its prices. *Id.*, Ex. H (Mylan 8/2/07 Dep.) at 194:18-195:15. It is not and has not been Mylan's practice or policy to consider State Medicaid reimbursement formulas or payments when reporting AWP and WAC to pricing compendia. *Id.*, Ex. K (Mylan 11/26/07 Dep.) at 15:15-18:13. It is not and has not been Mylan's practice or policy to attempt to ensure or maximize Medicaid reimbursement payments to pharmacies when selling or marketing its products to customers. *Id.*, Ex. D (Mylan 7/26/06 Dep.) at 28:12-29:10; Ex. L (Krinke 9/25/07 Dep.) at 238:13-239:03. Plaintiffs have not introduced any evidence on this present motion to sustain these allegations.

Plaintiffs' Reply to Statement #16:

Mylan cannot dispute the proposition set forth in statement #16. The Statement tracks Mylan's Answer to the FACC verbatim. It reads as follows:

Mylan denies the allegations in Paragraph 150 of the Consolidated Complaint, except admits that Mylan Pharmaceuticals Inc., and UDL Laboratories, Inc. were aware at various times, of the prices at which certain of their products were sold to providers and were aware, at various times, that FULs applied to certain generic products.

Mylan Answer at ¶ 150. While nothing more is required, Mylan admits in its response that Mylan knew the contract prices that Mylan negotiated with and entered into with certain of its customers, including certain large warehousing chains, and was aware that “FULs applied to certain generic products.”

The remainder of Mylan’s response is disputed and constitutes argument improper in a 56.1 opposition. No further reply is required.

Mylan’s Paid Wholesalers Chargebacks, Rebates and Discounts

16. At all times from 1997 to 2005, Mylan sold drugs to the three national wholesalers and/or one of their predecessor companies. *See* Mylan 30(b)(6) (Roman) 7/26/07 Dep. (Exhibit C) at 152:17-154:9; Exhibit U (Floyd 12/03/2008 Dep. Exhibit 51 (Mylan email, dated January 7, 2000, with attached customer price comparison worksheet identifying the national wholesalers); *see* Exhibit V (Mauro 6/27/08 Dep. Exhibit 1 (Account relationships document demonstrating contracts with various Mylan customers, including Cardinal, McKesson, and AmeriSource Bergen)); *see* Exhibit W (Mylan 30(b)(6) (Workman) 9/26/07 Dep. Exhibit 8 (Mylan letter to Cardinal, dated 7/19/99, providing AWP, WAC and contract prices for Mylan products)).

RESPONSE: Mylan does not dispute Plaintiffs’ SOF ¶ 17, except avers that Mylan has sold drugs to wholesalers and distributors other than Cardinal Health, McKesson, and AmerisourceBergen (f/k/a Bergen Brunswick), during the time period 1997 to 2005. Mylan disputes the characterization of Plaintiffs’ Exhibit U as an e-mail “dated January 7, 2000, with attached customer price comparison worksheet identifying the national wholesalers,” insofar as it appears to be a single page e-mail, dated January 31, 2000, with no attachments. Plaintiffs’ SOF, Ex. U. Mylan also disputes the characterization of Plaintiffs’ Exhibit W as “Mylan letter to Cardinal, dated 7/19/99, providing, WAC and contract prices for Mylan products,” insofar as it is misleading to suggest that Mylan invoiced its products to national wholesalers at prices other than WAC. Palermo Decl., Ex. U (H.D. Smith’s Full Line Wholesale Agreement); Ex. O (Workman 6/26/08 Dep.) at 104:15-107:15 (explaining full-line wholesaler agreement as representative of Mylan’s arrangements with wholesalers with respect to sales outside the wholesaler source program). Mylan further disputes Plaintiffs’ characterization of David Workman’s September 26, 2007 deposition as a 30(b)(6) deposition, insofar as Mr. Workman was deposed as an individual fact witness on September 26, 2007.

Plaintiffs’ Reply to Statement #17:

The parties agree that at all times from 1997 to 2005, Mylan sold drugs to wholesalers and distributors, including the three national wholesalers and/or one of their predecessor companies.

Plaintiffs further respond that despite Mylan's attempt to mis-characterize Exhibit W, the exhibit speaks for itself and clearly supports the proposition set forth in Statement #17. No further reply is required.

17. Mylan knew that its net prices to wholesalers and distributors were below WAC because of the discounts, rebates and chargebacks it paid. *See* Mylan 30(b)(6) (Roman) 7/26/06 Dep. (Exhibit C) at 69:06-71:21; *see* Cunard 10/26/07 Dep. (Exhibit J) at 95:09-17, 239:21-240:08 and 303:14-304:01; *see also* Exhibit X (Duda 4/16/08 Dep. Exhibit 3); Exhibit Y (Duda 4/16/08 Dep. Exhibit 20); *see* Mylan Laboratories, Inc. 30(b)(6) (David Workman) dated 6/26/08 Dep. (rough copy) (Exhibit Z) at 217:2-221:20; *see* Exhibit AA (Duda 4/16/08 Dep. Exhibit 9 (Mylan communication to AmerisourceBergen, dated November 20, 2001, demonstrating all contract prices below WAC)).

RESPONSE: Mylan disputes Plaintiffs' SOF ¶ 18 and Plaintiffs' implicit characterization of "net price" as a price that may be known to Mylan at the point of sale. *See, e.g.,* Palermo Decl., Ex. O (Workman 6/26/08 Dep.) at 109:18-113:11 (Mylan does not know the "net price" to a wholesaler "until after we have collected all our data or received all of those submissions from the various wholesalers or the points of distribution" and "there may be some instances where we don't receive that data because the wholesaler has sold to the customer at whatever price they have chosen to sell that at"). Mylan's WAC is and always has been a real transaction price in the marketplace at the point of sale and represents the price that the wholesaler is ultimately responsible for paying. *Id.*, Ex. P (Workman 10/15/08 Dep.) at 106:11-13 ("we invoice wholesalers at WAC" and "[t]hey're responsible for that invoice"). Mylan does not know at the point of sale which of the products shipped to the wholesaler at WAC is ultimately resold by the wholesaler or distributor to entities that have an indirect supply contract with Mylan or to entities that have a contract with the wholesaler under the wholesaler's own source program, such that Mylan's chargeback obligations would begin to accrue. *Id.*, Ex. P (Workman 10/15/08 Dep.) at 108:19-109:10 ("it is not a transaction or invoice that is paid in a vacuum" but rather there "are many moving parts to that invoice"). Discounts, rebates, chargebacks and promotional allowances are conditional and not realized at the point of sale. *Id.*, Ex. O (Workman 6/26/08 Dep.) at 110:01-113:11. With respect to sales outside the wholesaler source program or entities without a pre-existing contract with Mylan, at all relevant times, Mylan's WAC is and has been the price that wholesale customers pay Mylan with respect to those sales, less any conditional discounts such as the 2% prompt pay or a full-line credit that the wholesale customer may earn. *Id.*, Ex. P

(Workman 10/15/08 Dep.) at 104:17-107:15; Ex. U (H.D. Smith's Full Line Wholesale Agreement).

As set forth above, at all relevant times, Mylan's WAC has been consistent with the federal definition of WAC set forth in 42 U.S.C. § 1395w-3a, which states as follows:

The term "wholesale acquisition cost" means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

42 1396 § 1395w-3a (effective December 8, 2003). The WAC is "not an average" but a price that is actually paid by wholesalers and thus "a price point that is representative of the wholesale acquisition cost." *See also* Palermo Decl., Ex. P (Workman 10/15/08 Dep.) at 103:13-104:10.

Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. have also calculated and reported their "net prices to wholesalers and distributors" that take into account discounts, rebates, chargebacks and any other price adjustments, in the form of AMPs, pursuant to the federal rebate agreements. Palermo Decl., Ex. F (MPI rebate agreement) at § I(a) (emphasis added). AMP is defined under the rebate agreement as "the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade" and includes "cash discounts allowed and all other price reductions ... which reduce the actual price paid." *Id.*, Ex. F (MPI rebate agreement) at § I(a) (emphasis added). The AMP, by necessity, is a price that is computed later in time and after the initial sales transaction with the customer takes place, because the conditional discounts, rebates and chargebacks are not realized at the point of sale. *Id.*, Ex. F (the AMP for a quarter "must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized"). Consistent with the federal definition of WAC, Mylan's WAC has not included and does not include the net effect of discounts, chargebacks, rebates, and other cost adjustments which cannot be determined until after (and sometimes years after) the date of original sale. *See id.*, Ex. D (Mylan 7/26/06 Dep.) at 69:2-70:16; Ex. H (Mylan 8/2/07 Dep.) at 176:12-177:7; Ex. I (Cunard 10/26/2007 Dep.) at 276:1-12. Such discounts and rebates cannot be determined on the date of the invoice because by their very nature they can only be earned after the transaction is complete, including for example, prompt pay discounts which are based on speed of payment, and performance-based rebates based on volume purchasing over a period of time. *See id.* Moreover, the rebate agreement evinces an understanding and expectation by the industry and the parties to the agreement, including New York Medicaid, that manufacturers would be issuing discounts, rebates, chargebacks and "other price reductions," which would be reflected in their AMPs but not in their WACs. *Id.*, Ex. F (MPI rebate agreement) at § I(a); *see also* 42 U.S.C. § 1396r-8.

None of the testimony or documents cited by Plaintiffs disputes the fact that Mylan's WAC has, at all relevant times, represented the price to the wholesaler at the point of sale and is the price that Mylan knows the wholesaler to be responsible for paying, irrespective of any conditional discounts or credits that may be earned at a later time. *See, e.g.*, Plaintiffs' SOF, Ex. C (Mylan's 30(b)(6) designee explaining the chargeback process); Ex. J (Mr. Cunard explaining Mylan's contract pricing to a retail pharmacy chain); Ex. X (spreadsheet identifying WAC with the invoice price); Ex. Y (e-mail discussion concerning contract prices for a drug distributor's source program); Ex. Z (Mr. Workman explaining contract prices for a drug distributor's source program and explaining that the distributor is nonetheless invoiced at WAC); and Ex. AA (letter concerning select contracts serviced by AmerisourceBergen eligible for certain Mylan products). Mylan further disputes Plaintiffs' characterization of David Workman's September 26, 2007 deposition as a 30(b)(6) deposition, insofar as Mr. Workman was deposed as an individual fact witness on September 26, 2007.

Plaintiffs' Reply to Statement #18:

Mylan's response as to statement #18, is a transparent attempt to obfuscate a basic indisputable proposition, *i.e.*, that Mylan knew that its net prices to wholesalers and distributors were below WAC due to the chargebacks, rebates and discounts Mylan paid that Mylan did not account for in its WAC. The cited record evidence, testimony of Mylan's corporate designee, speaks for itself:

A. Let me tell you how it works. When we sell drugs to a wholesaler, we will invoice them at WAC, which is the wholesale acquisition cost for the drug. . . . They resell the drugs to pharmacies or hospitals or other – sometimes to other wholesalers. . . . [I]n fact, pretty often they will sell the drug to a company that we have a contract with where in our contract with that other company we have said: Hey, our drug is available at this wholesaler. We won't ship it to you, go get it from the wholesaler. And when you do, here's what your price will be.

And if the price to that customer is lower than WAC, then the customer getting the drug pays that agreed-upon price to the wholesaler. Well, if the wholesaler has paid us WAC and got less than WAC, the wholesaler will then send what's called a chargeback to Mylan to credit them the difference to make sure that the wholesaler has been kept whole in that process. ***So once you net out a chargeback, for example, you could say that the wholesaler didn't end up paying WAC ultimately for the drug.***

Now, there's also other forms – or other features of these agreements with the wholesalers like prompt pay discounts. If they pay us within 60 days, for example, they can get a 2 percent prompt pay discount that gets put in the mix. There are ***other forms of incentive rebates and things of that nature that get built into these agreements with the wholesalers that ultimately in a net kind of***

way bring the price the wholesaler paid down below WAC. But we do actually charge WAC and invoice at WAC as part of those transactions.

...

A. We may have an agreement that if the wholesaler sells a certain amount of our product, that they can earn an incentive rebate based on the volume that they've sold.

...

[I]f a wholesaler agrees to run a special promotion on our product, on a particular product group of products, we would pay them an incentive to do that, pick up the cost of that promotion or something, and that ends up increasing the sales. Those are the ones that come to mind.

Mylan 30(b)(6) (Roman) 7/26/06 Dep. (Exhibit C) at 69:06-71:21 (emphasis added). *See also* Cunard 10/26/07 Dep. (Exhibit J) at 95:09-17 ("But to answer, yes, the majority of sales to wholesaler and distributor range would have discounts applied to the WAC price.")

The reminder of Mylan's response is disputed and constitutes argument improper in a 56.1 opposition.

Mylan's Published AWP's and WACs Had No Relationship to Actual Prices

18. Mylan knows that none of its customers pay AWP for generic drugs. *See* Krinke 6/11/08 Dep. (Exhibit H) at 488:19-22; *see also* Mylan, 2008 WL 5650859 at *8.

RESPONSE: Mylan disputes Plaintiffs' SOF ¶ 19, except avers that AWP is generally not a price at which Mylan *sells* its drugs to its own customers. As Mylan's 30(b)(6) designee, Brian Roman, testified:

A. ... WAC, for example, wholesale acquisition cost, that is an invoice price for the drugs. AWP is not a price at which Mylan sells its drugs to its customers. So I've got an issue with the way you worded your question.

Q. Okay. Well, let's establish one thing based on your last answer. You do agree with me, sir, that the term "average wholesale price" is not the price at which Mylan has ever sold any drugs to its customers?

A. I can't be categorical about it. We've been in business 45 years and we sell about 150 different drugs today. So I don't know whether Mylan has sold products at AWP to its customers. It's possible we have at some point. But as a general matter, AWP is not a price at which Mylan sells Mylan's products to Mylan's customers. It doesn't mean it's not a price at which our products are sold downstream. The pharmacy may charge AWP to its customer, for example.

Palermo Decl., Ex. D (Mylan 7/26/06 Dep.) at 50:06-20. Plaintiffs' citation to Mr. Krinke's deposition testimony in support of its contention is misleading, as Mr. Krinke only testified that he "personally" did not know of a customer that purchased drugs at AWP. *See* Plaintiffs' SOF, Ex. H. Mr. Krinke also testified that he had no day-to-day involvement in setting AWP's or WAC's for Mylan's drugs. *Id.*, Ex. V (Deposition of Stephen Krinke dated June 11, 2008 ("Krinke 6/11/08 Dep.)) at 475:05-14; Ex. L (Krinke 9/25/07 Dep.) at 71:15-72:21, 147:11-19. Mylan also objects to Plaintiffs' SOF ¶ 19, and specifically Plaintiffs' citation to the Court's opinion in *Commonwealth of Massachusetts v. Mylan Laboratories, et al.*, 2008 WL 5650859 (D. Mass. Dec. 23, 2008), insofar as it quotes the Court's opinion out of context and calls for an improper legal conclusion not supported by the facts in the record.

Mylan also objects to Plaintiffs' SOF ¶ 19 and any contention that Plaintiffs understood AWP to represent the average of actual prices paid by providers at all times throughout the relevant time period. For example, during the Fifth Annual 340B Coalition Conference held on July 11-13, 2001, attended by several Mylan employees, the Director of Special Projects for the Office of the New York State Attorney General's Medicaid Fraud Control Unit gave a lengthy presentation concerning the use of AWP as a basis for pharmacy reimbursement, and the need to audit providers and create an "Average Selling Price" as a benchmark to use in calculating pharmacy reimbursement. Palermo Decl., Ex. W (Cunard 10/30/08 Dep. Ex. 25). To this day, New York Medicaid continues to reimburse providers based an AWP-based reimbursement formula. *See* Medicaid Prescription Reimbursement Information by State – Quarter Ending March 2009, available at <http://www.cms.hhs.gov/Reimbursement/Downloads/reimbursementchart1q2009.pdf>.

Plaintiffs' Reply to Statement #19:

Mylan admits that AWP is generally not a price at which Mylan sells its drugs to its customers. Mylan's dispute of this Statement in any regard is baseless. Mylan's own 30(b)(6) witness testified that Mylan does not sell its products at AWP. The testimony is as follows:

THE WITNESS: Mylan does not sell its products to its customers at AWP.

...

MR. MULLINS: And it never has. Is that correct?

MR. ESCOBAR: Objection to the form.

THE WITNESS: It's hard for me to be categorical. We've been in business for 45 years, and as I said, now we sell 170 different drugs; but by and large, no, AWP is not a price at which Mylan sells or has sold its drugs to its customers.

MR. MULLIN: And certainly Mylan has never understood that AWP represented a price that Mylan was selling its product for. Correct?

MR. ESCOBAR: Objection to the form.

THE WITNESS: I don't think Mylan understood that AWP was a price that Mylan was selling its products to its customers or ever represented it to be that.

Mylan 30(b)(6) (Roman) 8/2/07 Dep.") ("Reply Exhibit D" attached hereto) at 129:2-20. Other record evidence is consistent. "Q. Do you know – do you know of anybody who is purchasing Mylan's drugs at the published average wholesale price? A. I personally do not." See Krinke 6/11/08 Dep. (Exhibit H) at 488:19-22.

Nor can Mylan dispute that this Court found that "Mylan generally invoices its customers at WAC, but admits that individual pharmacies may contract with Mylan for less than WAC. The evidence indicates that Mylan never charged its customers AWP, and that Mylan's WACs were not related to its contract prices." *Mylan* 608 F. Supp. 2d at 137 (citations omitted).

The remainder of Mylan's response is disputed and constitutes argument improper in a 56.1 opposition. No further reply is required.

19. The WAC that Mylan reported or caused to be reported does not account for chargebacks and discounts paid by Mylan to wholesalers. See *Mylan* 30(b)(6) (Roman) 7/26/06 Dep. (Exhibit C) at 149:23-150:16; see also *Mylan*, 2008 WL 5650859 at *8.

RESPONSE: Mylan disputes Plaintiffs' SOF ¶ 20, insofar as Mylan has not "caused to be reported" WAC by pricing compendia. Mylan does not publish AWP or WAC, but rather reports its AWP and WACs to third party pricing compendia, such as First DataBank, RedBook and Medi-Span. Palermo Decl., Ex. C (Mylan 6/26/08 Dep.) at 28:19-29:02. The AWP and WACs published by third party pricing compendia, such as First DataBank, may not necessarily reflect the AWP and WACs reported by Mylan. *Id.*, Ex. C (Mylan 6/26/08 Dep.) at 21:08-22:06.

The undisputed evidence in the record shows that Red Book and Medi-Span did not publish WACs for Mylan drugs. As Mylan's 30(b)(6) designee, Dave Workman, testified:

Q. So you're not suggesting that WAC was a price that Red Book didn't publish?

A. Yes, I am not claiming that Red Book doesn't publish WAC's, however, I don't believe they publish Mylan Pharmaceutical WAC's.

Q. So do you know whether Red Book's failure to publish Mylan WAC's is a function of Mylan's direction?

A. I don't know.

Q. So as we sit here today you know that Red Book doesn't publish WAC's for Mylan but you don't know why; correct?

A. That's correct.

Id., Ex. C (Mylan 6/26/08 Dep.) at 30-31; *see also* Exs. Q, R & S (FUL calculation spreadsheets for CMS indicating Red Book and Medi-Span WAC values associated with Mylan's clonazepam, lorazepam and metoprolol are zeroed out).

Mylan also avers that, at all relevant times, the WAC that it reported to the pricing compendia has been consistent with the federal definition of WAC set forth set forth in 42 U.S.C. § 1395w-3a:

The term "wholesale acquisition cost" means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

42 1396 § 1395w-3a (effective December 8, 2003).

To the extent Plaintiffs contend that a price that accounts for chargebacks and discounts issued by Mylan to wholesalers should have been reported, Mylan has also reported its AMP on a quarterly basis to CMS and various states that have requested it, including the State of New York, pursuant to the federal rebate agreement and any state supplemental rebate agreements entered into by Mylan Pharmaceuticals Inc. and/or UDL Laboratories, Inc. Palermo Decl., Exs. F & G (MPI rebate agreement, UDL rebate agreement); *see also* Ex. X (Mylan Pharmaceuticals Inc.'s supplemental rebate agreement with New York State Elderly Pharmaceutical Insurance Coverage Program, dated October 3, 1991); Ex. Y (Mylan Pharmaceuticals Inc.'s supplemental rebate agreement with New York State Department of Social Services, dated October 2, 1991).

Plaintiffs' Reply to Statement #20:

The parties agree that Mylan reported its AWP's and WAC's to third-party Compendia such as First DataBank, Redbook and MediSpan. Mylan does not dispute that the WAC's it reported did not account chargebacks, rebates and other discounts or reductions in price. The record evidence of Mylan's 30(b)(6) witness speaks for itself as follows:

A. WAC – the WAC is the price at which the wholesaler is invoiced, and it does not include chargebacks, it doesn't include discounts off of WAC. It's that reference point at which the wholesaler is invoiced. And then, as I've said, there are other things that come into that if what you are trying to do is to determine the net amount of money that the wholesaler paid us for a particular product.

Q. If I were trying to determine the net amount of money the wholesaler paid, I would need to take the WAC invoice price minus whatever credits that particular wholesaler received; is that correct?

A. Credits or adjustments?

Q. Right.

A. Sure. The WAC is not the net amount that the wholesaler pays Mylan, it's the invoice amount.

See Mylan 30(b)(6) (Roman) 7/26/06 Dep. (Exhibit C) at 149:23-150:16.

The remainder of Mylan's response is disputed and constitutes argument improper in a 56.1 opposition. No further reply is required.

20. Mylan did not account for prompt pay discounts, rebates and credits in its reported prices. Mylan Answer at ¶155.

RESPONSE: Mylan disputes Plaintiffs' SOF ¶ 21, insofar as it mischaracterizes Mylan's answer to ¶ 155 of Plaintiffs' Revised First Amended Complaint. See Mylan's Answer, ¶ 155. As stated in Mylan's answer, Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. offered prompt pay discounts, rebates and credits and that such discounts, rebates and credits were not used to set some reported prices. *Id.*, ¶ 155 (emphasis added). As set forth above, at all relevant times, Mylan's AWP has been a price set in reference to the brand AWP and any generic competitor's AWP at the time of launch. See *supra*, ¶ 9. At all relevant times, Mylan's WAC has been the invoice price to wholesalers and represents the price that is being charged to its wholesale customers at the time of sale. *Id.*, Ex. P (Workman 10/15/08 Dep.) at 103:03-24; Ex. A (Mylan 11/16/06 Dep.) at 230:20-233:16; Ex. H (Mylan 8/2/07 Dep.) at 175:15-21, 181:09-182:11. To the extent Mylan has negotiated contract prices at the time of launch, Mylan would consider such prices in relation to Mylan's potential chargeback obligations, prompt pay discounts, as well as the manufacturer cost (material-labor-overhead) for the product in setting the WAC. *Id.*, Ex. M (Workman 9/26/07 Dep.) at 98:02-104:13; Ex. H (Mylan 8/2/07 Dep.) at 182:01-11.

Mylan also avers that its reported AMP has included any prompt pay discounts, rebates and credits that have been actually earned or realized, which Mylan reported on a quarterly basis to CMS and various states that have requested it, including the State of New York, pursuant to the federal rebate agreement and any state supplemental rebate agreements entered into by Mylan Pharmaceuticals Inc. and/or UDL Laboratories, Inc.

Palermo Decl., Exs. F & G (MPI rebate agreement, UDL rebate agreement); *see also* Ex. X (NY EPIC agreement); Ex. Y (NYS supplemental rebate agreement).

Plaintiffs' Reply to Statement #21:

Mylan's Answer to Plaintiffs' FACC at ¶ 155 "admits that, from time to time, Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. offered prompt payment discounts, rebates and credits and that such prompt pay discounts, rebates and credits were not used to set some reported prices."

The remainder of Mylan's response is disputed and constitutes argument improper in a 56.1 opposition. No further reply is required.

21. Mylan admits that it controls its discounting policies. Mylan Answer at ¶156.

RESPONSE: Mylan does not dispute Plaintiffs' SOF ¶ 22, except avers that Mylan does not have a pre-determined policy or practice of issuing discounts to its customers. Rather, the discounts, rebates or credits issued to customers are the product of negotiations between Mylan and its wholesale customers and/or Mylan and its indirect customers, and may vary customer-by-customer or product-by-product:

Q. Okay. The -- I suppose it's at least theoretically possible based on what you've told me that a wholesaler could get a collection of discounts that total five or six percent? And let me just go --

* * *

A. That's what I'm trying to clarify is that each of these are negotiated individually and, no, we would not have multiple fee associated with that WAC that would continue to add up.

Q. I see. So you would have -- you have the 2 percent and then you might have one other fee, which is supposed to take into consideration the other attributes?

A. Yes.

Palermo Decl., Ex. O (Workman 6/26/08 Dep.) at 79:20-85:07 ("every wholesaler or their negotiation of what [the discounts or service fees] may be could be different from customer to customer or product by product"); Ex. I (Cunard 10/26/2007 Dep.) at 64:8-16, 92:16-93:4.

Plaintiffs' Reply to Statement #22:

The parties agree that Mylan controls its discounting policies. No further reply is required.

22. Manufacturers knew published WACs were false. *Mylan*, 2008 WL 5650859 at *26.

RESPONSE: Mylan disputes Plaintiffs' SOF ¶ 23. As set forth above, at all relevant times, Mylan's WAC is and has been a real transaction price in the marketplace and represents the price that the wholesaler is ultimately responsible for paying. *Id.*, Ex. P (Workman 10/15/08 Dep.) at 106:11-13;118:24-119:08. Mylan does not know at the point of sale which of the products shipped to the wholesaler at WAC is ultimately resold by the wholesaler or distributor to entities that have an indirect supply contract with Mylan or to entities that have a contract with the wholesaler under the wholesaler's own source program, such that Mylan's chargeback obligations would begin to accrue. *Id.*, Ex. P (Workman 10/15/08 Dep.) at 118:24-119:08 (a wholesaler may "be responsible for the full WAC, because we would not be receiving a chargeback either for a third party or for their source program"). Mylan's WAC is also consistent with the federal definition of WAC set forth in 42 U.S.C. § 1395w-3a, which states as follows:

The term "wholesale acquisition cost" means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

42 1396 § 1395w-3a (effective December 8, 2003). Mylan's WAC is "not an average" but a price that is actually paid by wholesalers and thus "a price point that is representative of the wholesale acquisition cost." *See also* Palermo Decl., Ex. P (Workman 10/15/08 Dep.) at 103:13-104:10.

Mylan also objects to Plaintiffs' SOF ¶ 23, and specifically Plaintiffs' citation to the Court's opinion in *Commonwealth of Massachusetts v. Mylan Laboratories, et al.*, 2008 WL 5650859 (D. Mass. Dec. 23, 2008), insofar as it quotes the Court's opinion out of context and calls for an improper legal conclusion not supported by the facts in the record. Plaintiffs' reliance on *Commonwealth of Massachusetts v. Mylan Laboratories, et al.*, 2008 WL 5650859 (D. Mass. Dec. 23, 2008), is also misplaced because there has been no finding by the jury or this Court that Mylan reported false prices or knew that the published WACs were false. *Id.*, at *26 ("there still exists a genuine issue as to whether the defendants acted knowingly and willfully during those time periods"). Indeed, the Court found that defendants in the Massachusetts pricing litigation "have produced sworn

testimony that they believed WACs to be merely an invoice price and that they used it as such, as well as some evidence that some others understood WAC in the same way,” and thus “there is sufficient evidence for a verdict for the Defendants.” *Id.*, at *25.

Plaintiffs’ Reply to Statement #23:

It is indisputable that this Court found that “Mylan generally invoices its customers at WAC, but admits that individual pharmacies may contract with Mylan for less than WAC. The evidence indicates that Mylan never charged its customers AWP, and that Mylan’s WACs were not related to its contract prices.” (citations omitted) *Mylan* 608 F. Supp. 2d at 137.

The remainder of Mylan’s response is disputed and constitutes argument improper in a 56.1 opposition. No further reply is required.

23. Mylan reported WACs that were grossly out of whack with the prices that were actually paid. *Mylan*, 2008 WL 5650859 at *26.

RESPONSE: Mylan disputes Plaintiffs’ SOF ¶ 24. As set forth above, at all relevant times, Mylan’s WAC is and has been a real transaction price in the marketplace and represents the price that the wholesaler is ultimately responsible for paying. *Id.*, Ex. P (Workman 10/15/08 Dep.) at 106:11-13; 118:24-119:08. Mylan does not know at the point of sale which of the products shipped to the wholesaler at WAC is subsequently resold by the wholesaler or distributor to entities that have an indirect supply contract with Mylan or to entities that have a contract with the wholesaler under the wholesaler’s own source program, such that Mylan’s chargeback obligations would begin to accrue. *Id.*, Ex. P (Workman 10/15/08 Dep.) at 118:24-119:08. As set forth above, Mylan’s WAC is also consistent with the federal definition of WAC set forth in 42 U.S.C. § 1395w-3a, which states as follows:

The term “wholesale acquisition cost” means, with respect to a drug or biological, the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

42 1396 § 1395w-3a (effective December 8, 2003). Mylan's WAC is "not an average" but a price that is actually paid by wholesalers and thus "a price point that is representative of the wholesale acquisition cost." *See also* Palermo Decl., Ex. P (Workman 10/15/08 Dep.) at 103:13-104:10.

Mylan also objects to Plaintiffs' SOF ¶ 24, and specifically Plaintiffs' citation to the Court's opinion in *Commonwealth of Massachusetts v. Mylan Laboratories, et al.*, 2008 WL 5650859 (D. Mass. Dec. 23, 2008), insofar as it quotes the Court's opinion out of context and calls for an improper legal conclusion not supported by the facts in the record. Plaintiffs' reliance on this Court's opinion in *Commonwealth of Massachusetts v. Mylan Laboratories, et al.*, 2008 WL 5650859 (D. Mass. Dec. 23, 2008), is also misplaced insofar as the 4 out of the 5 Mylan drugs selected for FUL-related discovery were not at issue in the Massachusetts pricing litigation. *Id.* Mylan further disputes that Mylan's WACs are "grossly out of whack" with the "prices that were actually paid," insofar as the plaintiff in the Massachusetts litigation compared the WAC against the AMP, and because AMP represents a statutory average that is calculated months after the sale or transaction occurs and may not necessarily represent a price (*e.g.*, contract price) that has actually been paid. Palermo Decl., Ex. F (MPI rebate agreement).

Plaintiffs' Reply to Statement #24:

Mylan cannot dispute that in *Mylan*, 608 F. Supp. 2d 127, the court found that "defendants [including Mylan] reported WACs that were grossly out of whack with the prices that were actually paid." *Id.* at 156.

The remainder of Mylan's response is disputed and constitutes argument improper in a 56.1 opposition. No further reply is required.

24. Mylan set pricing tiers for various customers, which were always below WAC. *See* Cunard 10/30/08 Dep. (Exhibit F) at 258:5-13, 260:2-23; Exhibit BB (Cunard 10/30/08 Dep. Exhibit 22 (Mylan email, dated September 16, 2001, demonstrating for various products every tier of pricing below WAC)); *see* Deposition of Joseph Duda dated 4/16/08 (Exhibit CC) at 157:14-20; *see also* Exhibit DD (Duda 4/16/08 Dep. Exhibit 2) and Exhibit EE (Duda 4/16/08 Dep. Exhibit 5) (Mylan documents demonstrating all contract prices or bid prices that were less than WAC).

RESPONSE: Mylan disputes Plaintiff's SOF ¶ 25, except avers that there may be contract prices offered to customers below the WAC with respect to those sales of Mylan's drugs made through the wholesaler source program and/or to a customer with an

indirect supply contract with Mylan, where chargeback obligations would accrue. Palermo Decl., Ex. P (Workman 10/15/08 Dep.) at 104:11-107:15. Mylan further disputes Plaintiffs' SOF ¶ 25, insofar as it suggests or implies that Mylan had implemented "pricing tiers for various customers" based on customer class of trade. The "pricing tiers" referred to by Plaintiffs simply reflect the "starting points for negotiation" with respect to certain drugs that are not specific to any customer, that do not necessarily correspond to the contract price ultimately entered into by Mylan, and that do not apply to any sales that are made outside the wholesaler source program and/or to an entity that does not have an indirect supply agreement with Mylan. *Id.*, Ex. Z (Deposition of Joseph Duda dated April 16, 2008 ("Duda 4/16/08 Dep.")) at 155:3-11 (these are "reference prices that were A, B, C and D that would help facilitate the negotiation of contract instead of going each individual NDC, you know, to create a price"; Ex. T (Cunard 10/30/08 Dep.) at 262:3-11 ("[t]his is all just – just projected and -- and just analytical models, trying to figure it out").

As explained by Mr. Workman, at all relevant times, Mylan's WAC has been a real transaction price in the marketplace and represents the price that the wholesaler is ultimately responsible for paying. *Id.*, Ex. P (Workman 10/15/08 Dep.) at 104:11-107:15. There may be instances where Mylan negotiates a contract price with the wholesaler for sales made through the wholesaler's source program, originally initiated by a wholesaler and not Mylan:

A. ... There was an initiative by a wholesaler that occurred where they had warehouses full of multiple manufacturers for the same product, and they wanted to eliminate multiple manufacturers for the same product in their warehouse, and I believe the customer was Bergen Brunswig, and they created an auto-sub/source program where they contacted all the manufacturers and they said, we are going to put our entire stocking portfolio out to bid to all the manufacturers, and this is how you respond to this bid, and this is what transactions you need to perform. And it was competitive bid processing, and from what we understood, the most aggressive or the lowest price won their warehouse space, and instead of a pharmacy ordering up Mylan's product, they would just order up the product in general, and whoever's product was stored in inventory in that warehouse space would then be shipped to their customers. So, that was the evolution of the source program.

Today, we invoice wholesalers at WAC. They're responsible for that invoice. They sell to pharmacies under a source program. They sell to pharmacies that are members under our third-party contracts. They also sell to pharmacies that are on neither a third-party contract or their source program. When they do sell a product out under their source program or under a third-party contract, at a designated negotiated contract price, a chargeback is processed, and a chargeback is the difference between WAC and that contract price. If they sell it to a pharmacy that is not a part of a third-party contract or not a part of their source program, we would not

receive a chargeback for that, so they would be responsible for that invoice.

Id., Ex. P (Workman 10/15/08 Dep.) at 104:11-107:15. The standard contract with wholesalers for drugs not sold under the wholesaler source program is the full-line wholesaler agreement, where wholesalers are generally eligible to earn a 2% prompt pay and a 15% monthly credit (as a full line allowance on all purchases). *Id.*, e.g., Ex. U (H.D. Smith's Full Line Wholesale Agreement).

Plaintiffs have not alleged in their Revised First Amended Complaint that such arrangements with wholesalers under their source program are in any way improper or illegal. *See generally* Plaintiffs' Revised First Amended Complaint. Similarly, Plaintiffs' citation of the testimony or documents in support of their contention is entirely misleading and does not imply any wrongdoing by Mylan. *See* Plaintiffs' SOF, Ex. BB (e-mail chain discussing bid price to McKesson for sales to its source program); Ex. CC (April 16, 2008 deposition testimony of Joseph Duda inaccurately cited by Plaintiffs as a "Mylan document"); Ex. DD (spreadsheet containing proposed bid price to Rite Aid, a retail pharmacy chain and not a wholesaler); and Ex. EE (chart listing the "MLO," "AWP," "WAC," "WAC – 20%," and "B" price with respect to erythromycin, which is not a drug at issue on Plaintiffs' present motion). Mr. Duda has further testified that to the extent prices were "tiered" in any way, they merely represent "reference prices...[that] would help facilitate the negotiation of contract instead of going each individual NDC, you know, to create a price." *Id.*, Ex. Z (Duda 4/16/08 Dep.) at 155:3-11; *see also* Ex. T (Cunard 10/30/08 Dep.) at 262:3-11 ("[t]his is all just – just *projected* and -- and just analytical models, trying to figure it out") (emphasis added).

Lastly, Plaintiffs' contention that all Mylan's prices to customers were below WAC is also contradicted by the undisputed evidence in this case. In a February 3, 1998 letter to client Martijn Trading Company, for example, Mylan charged a price of 20% above the WAC for various strengths of Mylan's lorazepam. *Id.*, Ex. AA (NYMylan00053292); Ex. BB (NYMylan00053091-96) (contrast WAC prices contained in price notification letter sent to Martijn Trading Company indicating increase in direct invoice price for Mylan's lorazepam against separate notification letter sent to Burling Drug indicating increase). This is further corroborated by Mr. Workman, who testified that "WAC should be higher than a contract price *in which chargebacks are received*, however, there could be contract prices higher than WAC." *Id.*, Ex. M (Workman 9/26/07 Dep.) at 102:8-104:2 ("[e]very product and every customer is individually negotiated").

Plaintiffs' Reply to Statement #25:

Mylan admits there "may be contract prices offered to customers below the WAC with respect to those sales of Mylan's drugs made through the wholesaler source program and/or to a customer with an indirect supply contract with Mylan, where chargeback obligations would

accrue.” Mylan admits it has customer “pricing tiers.” Mylan admits that sales to wholesalers governed by third-party contracts or source program contracts are below WAC. Mylan admits the standard contract with wholesalers for drugs not sold under the wholesaler source program is the full-line wholesaler agreement, where wholesalers are generally eligible to earn a 2% prompt pay and a 15% monthly credit (as a full line allowance on all purchases). *Id.*, e.g., Ex. U (H.D. Smith’s Full Line Wholesale Agreement). The remainder of Mylan’s response is disputed and constitutes argument improper in a 56.1 opposition. No further reply is required.

OIG Guidelines

25. Mylan knew that under the OIG Guidelines manufacturers were expected to provide accurate pricing data. *See* Exhibit FF (Cunard 10/30/08 Dep. Exhibit 2 (Mylan email string from October 2002 describing the expectations of the OIG guidelines)); *see also* Exhibit GG (Cunard 10/30/08 Dep. Exhibit 3 (OIG Compliance Program Guidance for Pharmaceutical Manufacturers)).

RESPONSE: Mylan does not dispute Plaintiffs’ SOF ¶ 26, except avers that Mylan has fully complied with the policies, procedures, code of conduct, and any other recommendations set forth in the OIG Compliance Program Guidance for Pharmaceutical Manufacturers (“OIG Guidelines”). 68 Fed. Reg. 23731 (May 5, 2003). Plaintiffs have not introduced any evidence demonstrating that Mylan “purposefully manipulate[d] the AWP to increase its customers’ profits” or set its AWP in order to “manipulate the ‘spread’ to induce customers to purchase its product.” *Id.* Rather, all present and former employees of Mylan have testified that it has not been Mylan’s practice or policy to consider reimbursement payments to providers when setting or reporting the AWP for its products. *Id.*, Ex. K (Mylan 11/26/07 Dep.) at 17:15-18:13; Ex. H (Mylan 8/2/07 Dep.) at 181:03-22. It has not been Mylan’s practice or policy to attempt to ensure or maximize Medicaid reimbursement payments to pharmacies when selling or marketing its products to customers. *Id.*, Ex. D (Mylan 7/26/06 Dep.) at 28:12-29:10; Ex. L (Krinke 9/25/07 Dep.) at 238:13 – 239:03. Indeed, the primary focus of Mylan’s sales and marketing efforts is not aimed “at the back end of reimbursement” but rather is designed to “make sure our customers can get our product, that it’s not on back order, that we’re able to fill their orders, get it to them quickly, get them a high quality product at a price that is competitive.” *Id.*, Ex., D (Mylan 7/26/06 Dep.) at 28:12-29:10; *see also* Ex. CC (e-mail chain from Mylan sales representative Edgar Escoto to Tony Mauro indicating a sales pitch focused on Mylan’s quality, reliability and choice of “premium raw suppliers so that we can keep our partners supplied,” and commending Mylan’s sales training program). As Mr. Cunard, former VP of sales and marketing testified:

Q. And what were the general basis (sic) on which you perceived that you competed with other companies with respect to the sale of pharmaceutical products?

A. As indicated earlier, price, supply, value-added services, CE programs
* * *

A. Price, supply, value-added services such as continuing education programs, quality of product, reliability, reputation.

Id., Ex. I (Cunard 10/26/07 Dep.) at 273:7-16.

The corporate compliance department at Mylan has also implemented periodic training programs to ensure that Mylan employees comply with the “[l]aws, regulations, ethics...[Mylan’s] own code of ethics, [and] standards for interactions with health care providers.” Palermo Decl., Ex. d (Mylan 7/26/06 Dep.) at 134:1-4. Mylan also avers that the OIG Guidelines do not define AWP or WAC, or instruct manufacturers as to how to calculate or report AWP or WAC. *Id.* Mylan further disputes the relevance of the OIG Guidelines to this case as they are only “intended to present voluntary guidance to the industry and not to represent binding standards for pharmaceuticals manufacturers. Plaintiffs’ SOF, Ex. FF.

Plaintiffs’ Reply to Statement #26:

The parties agree that Mylan knew that under the OIG Guidelines manufacturers were expected to provide accurate pricing data.

The remainder of Mylan’s response is disputed, irrelevant and constitutes argument improper in a 56.1 opposition. No further reply is required.

Mylan Marketed the Spread

26. Mylan knew its customers evaluated and made purchasing decisions based on the reimbursement spread between the customers’ cost and the reimbursement price of an AWP, WAC or FUL/MAC. *See* Exhibit HH (Cunard 10/26/07 Dep. Exhibit 20 (Omnicare email to Mylan, dated April 2001, requesting AWP and WAC updates and explaining that Omnicare monitors Medicaid changes and FULs in the states where it operates)).

RESPONSE: Mylan disputes Plaintiffs’ SOF ¶ 27. All present and former employees of Mylan have testified that it has not been Mylan’s practice or policy to consider reimbursement payments to providers when setting or reporting AWP for its products. *Id.*, Ex. K (Mylan 11/26/07 Dep.) at 17:15-18:13; Ex. H (Mylan 8/2/07 Dep.) at 181:03-22. It has not been Mylan’s practice or policy to attempt to ensure or maximize Medicaid

reimbursement payments to pharmacies when selling or marketing its products to customers. *Id.*, Ex. D (Mylan 7/26/06 Dep.) at 28:12-29:10; Ex. L (Krinke 9/25/07 Dep.) at 238:13-239:03. Mylan has not received any part of the reimbursement amount paid by Medicaid. *See Id.*, Ex. I (Cunard 10/26/07 Dep.) at 272:9-15. Indeed, the primary focus of Mylan's sales and marketing efforts is not aimed "at the back end of reimbursement" but rather is designed to "make sure our customers can get our product, that it's not on back order, that we're able to fill their orders, get it to them quickly, get them a high quality product at a price that is competitive." *Id.*, Ex. D (Mylan 7/26/06 Dep.) at 28:12-29:10; *see also* Ex. CC (e-mail chain from Mylan sales representative Edgar Escoto to Tony Mauro indicating a sales pitch focused on Mylan's quality, reliability and choice of "premium raw suppliers so that we can keep our partners supplied," and commending Mylan's sales training program). Mylan's primary purpose for reporting AWP to the pricing compendia was "to make the marketplace aware that the products were being marketed and were available for sale." *See Id.*, Ex. KK (Korman 11/26/07 Dep.) at 17:15-18:2.

The single document cited by Plaintiffs does not demonstrate any knowledge by Mylan, let alone former employees at Mylan, that Omnicare was seeking to benefit from the spread. Plaintiffs' SOF, Ex. HH. In fact, when asked about this document, Mr. Cunard testified:

A. I asked Mr. Duda to contact the customer to facilitate making this happen just because it was a customer and they had requested information that we could relatively easily provide. As to what their use for that information was, it was insignificant to me.

Id., Ex. II (Cunard 10/26/07 Dep.) at 263:8-263:13. Plaintiffs' attempt to impute wrongdoing on certain Mylan employee(s) based on receipt of a customer's request for Mylan's AWP and WAC, which is publicly available information that Mylan generally shares with its customers as well as the various pricing compendia, only demonstrates Plaintiffs' lack of evidence to sustain their claims against Mylan in this action.

Plaintiffs' Reply to Statement #27:

The record evidence speaks for itself. Mylan's response is disputed and constitutes argument improper in a 56.1 opposition. No further reply is required.

27. Mylan knew that reimbursement was important to its customers and even provided customers with recommendations regarding third-party reimbursement. *See* Deposition of Janet Floyd dated 12/3/08 ("Floyd 12/3/08 Dep.") (Exhibit II) at 55:22-56:12; *see also* Exhibit JJ (Floyd 12/3/08 Dep. Exhibit 14 (Collection of Mylan price agreements distributed to various customers on April 9, 1998, that furnish both AWP and WAC prices)); *see also* Exhibit KK (Cunard 10/26/07 Dep. Exhibit 12 (2000 Mylan email sent to a customer demonstrating Mylan's awareness of customer sensitivity to Medicaid reimbursement)).

RESPONSE: Mylan disputes Plaintiffs' SOF ¶ 28. As set forth above, it has not been Mylan's practice or policy to attempt to ensure or maximize Medicaid reimbursement payments to pharmacies when selling or marketing its products to customers. *Id.*, Ex. D (Mylan 7/26/06 Dep.) at 28:12-29:10; Ex. L (Krinke 9/25/07 Dep.) at 238:13-239:03. Indeed, the primary focus of Mylan's sales and marketing efforts is not aimed "at the back end of reimbursement" but rather is designed to "make sure our customers can get our product, that it's not on back order, that we're able to fill their orders, get it to them quickly, get them a high quality product at a price that is competitive." *Id.*, Ex. D (Mylan 7/26/06 Dep.) at 28:12-29:10; *see also* Ex. CC (email chain from Mylan sales representative Edgar Escoto); Ex. I (Cunard 10/26/07 Dep.) at 273:4-16. This is further corroborated by testimonies of former sales personnel at Mylan Pharmaceuticals Inc., including Mr. Mauro, a national accounts manager during the relevant time period, who testified:

Q. Would you agree that part of your job as vice president for sales and as a director of the NAMs, the national account managers, and so forth over several years, part of your job was to try to convince customers how they can increase their profits when they buy and sell Mylan drugs?

* * *

A. No, that was not something we did. The way we tried to promote our products to our customers were we were providing a broad offering of new items with a robust pipeline to keep them in service, and the company hasn't had a recall from a manufactured product in over 47 years.

Id., Ex. DD (Deposition of Tony Mauro dated October 31, 2008 ("Mauro 10/31/08 Dep.") at 278:4-18. As Bob Potter, the Vice President of sales and marketing at Mylan Pharmaceuticals Inc. during the relevant time period, also stated:

Q. And reimbursement was never a concern in all those years when you were selling product to your customers?

A. It may have been a concern on their point, but our point is we go with our best price, and they make the decision if they'd like to buy our product or not. There's other products available in the hundreds of products that we do have.

I think if you go down to the key, also to influence sales, on this sheet, the most important ones that we haven't talked about is the value of our product, where we haven't had any recalls, and that is a very important piece of our whole [selling] process.

Id., Ex. EE (Deposition of Bob Potter dated November 25, 2008 ("Potter 11/25/08 Dep.") at 77:12-78:3.

The documents and testimony cited by Plaintiffs do not in any way support their contention that Mylan "provided customers with recommendations regarding third-party reimbursement." Plaintiffs' Exhibit JJ is merely a series of form letters sent to customers

containing Mylan's AWP and WAC changes for certain products. Plaintiffs' SOF, Ex. JJ. When asked about these communications, Ms. Floyd testified that the sole purpose of the communication was to send notifications of changes to Mylan's "wholesale invoice price" or WAC, and nothing more. Plaintiffs' SOF, Ex. II. Simply put, Mylan did not attempt to make recommendations to customers concerning reimbursement. *Id.*

Plaintiffs' Exhibit KK, as Mr. Cunard testified at his deposition was not created because of any concern or belief about "customer sensitivity to Medicaid reimbursement" as Plaintiffs contend, but to address "confusion in the marketplace as there were two products that were the same molecule...but they were not interchangeable with one another." Palermo Decl., Ex. I (Cunard 10/26/07 Dep.) at 213:14-216:12. These documents do not lend any support to Plaintiffs' contention that Mylan recognized that third-party reimbursement was an overriding concern to customers or that Mylan made any reimbursement recommendations to customers. *Id.*, Ex. I (Cunard 10/26/07 Dep.) at 119:08-120:03 (the notion that there was a policy at Mylan to maximize reimbursement payments to pharmacies is "fundamentally flawed").

Plaintiffs' Reply to Statement #28:

Mylan's response is disputed and constitutes argument improper in a 56.1 opposition. No further reply is required.

Mylan's AMPs

28. At all times, from 1997 to 2005, Mylan has calculated on a quarterly basis the average manufacturer's price ("AMP") for all its products as required by the federal rebate statute. *See* Mylan 30(b)(6) (Roman) 7/26/06 Dep. (Exhibit C) at 81:07-13 and 130:06-23; *See* Mylan 30(b)(6) (Roman) 11/16/2006 Dep. (Exhibit B) at 38:16-39:12; Cunard 10/30/08 Dep. (Exhibit F) at 58:20-59:25; *see also* Mylan, 2008 WL 5650859 at *30.

RESPONSE: Mylan does not dispute Plaintiffs' SOF ¶ 29, except avers that Mylan has further reported its AMP to CMS and to various states that have requested it, including the State of New York. Palermo Decl., Exs. F & G; *see also* Ex. X (NY EPIC agreement); Ex. Y (NYS rebate agreement).

Plaintiffs' Reply to Statement #29:

The parties agree that at all times, from 1997 to 2005, Mylan has calculated on a quarterly basis the average manufacturer's price ("AMP") for all its products as required by the federal rebate statute.

Plaintiffs have no basis to dispute Mylan's Statement that it has provided AMPs to the New York EPIC program but note that the New York EPIC contract itself requires the Mylan AMPs to be treated confidentially. *See* Palermo Decl. Ex. X at Section V(a) (New York State EPIC Program Manufacturer Drug Rebate Agreement). Plaintiffs have no basis to dispute Mylan's Statement that it has provided AMPs in connection with the New York State Rebate program but note that the New York State Department of Social Services rebate contract with Mylan adopts the confidentiality provisions of the federal Medicaid rebate contract. *See* Palermo Decl. Ex. Y at Section II(f) (New York State Department of Social Services rebate agreement).

III DEFENDANTS' ADDITIONAL STATEMENTS OF MATERIAL FACTS OF RECORD AS TO WHICH THERE IS NO GENUINE ISSUE TO BE TRIED

30. The government, through the Department of Veterans Affairs and the Department of Defense, negotiates Federal Supply Schedule ("FSS") prices for federal purchases of pharmaceuticals. Palermo Decl., Ex. FF (United States General Accounting Office, Report to Congressional Requesters, "DOD AND VA PHARMACY: Progress and Remaining Challenges in Jointly Buying and Mailing Out Drugs," May 2001, GAO-01-588), at 8-10. The FSS contains prices at which federal buyers are able to purchase pharmaceuticals. FSS prices for generic drugs are negotiated based on contract price and term information for most favored customers, which is requested from and provided by Mylan. *See id.*

Plaintiffs' Response to Defendants' Statement #30:

Mylan's Statement #30 is irrelevant to plaintiffs' motion which concerns defendants' failures to report accurate prices. Plaintiffs dispute and object to Statement #30 to the extent that defendants seek to imply or suggest, by it, that defendants are not liable for the harm their false price reports caused Medicaid. Plaintiffs dispute and object to the Statement to the extent defendants seek to imply or suggest that plaintiffs had any knowledge, ability, duty or obligation to seek out any FSS pricing information to the extent that such was even available or could be understood or would be reflective of anything pertinent to plaintiffs. In further response,

plaintiffs dispute any attempt to suggest or imply that FSS such pricing information could be used for Medicaid reimbursement, contrary to New York law during the relevant period.. Plaintiffs further dispute that FSS pricing has any relevance for Medicaid whatsoever given that it is among the pricing expressly excluded from Best Price and other reporting requirements set forth in, for example, 42 U.S.C. 1396r-8. In further response, plaintiffs note that this Court has found:

As a general matter, the knowledge of one agency is not imputed to another agency of that government. Only “if there is some relationship between the agencies-either some reason for the agency without knowledge to seek the information or a reason for the knowledgeable agency to transmit the information” will one agency’s knowledge be imputed to another.

Mylan, F. Supp. 2d at 150 (citation omitted).

31. FSS prices are lower than the published prices alleged by Plaintiffs in their Exhibit A to SOF. *See id.*; U.S. Department of Veterans Affairs website, *available at* <http://www.pbm.va.gov/DrugPharmaceuticalPrices.aspx> (“VA Website”). The FSS prices are not confidential and recent prices are reported by the US Department of Veterans Affairs on their website. *See* VA Website. FSS prices are therefore known or knowable to New York. *See id.*

Plaintiffs’ Response to Defendants’ Statement #31:

Plaintiffs incorporate herein their response to defendants’ statement #30. No further response is necessary.

Dated: June 30, 2009

Respectfully submitted,

**City of New York and New York Counties in
MDL 1456 except Nassau and Orange by**

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CERTIFICATE OF SERVICE

I, James P. Carroll Jr., hereby certify that I caused a true and correct copy of the foregoing PLAINTIFFS' REPLY LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS AS TO MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC., AND UDL LABORATORIES, INC., to be served on counsel of record via electronic service pursuant to paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File and Serve for posting and notification to all parties.

Dated: June 30, 2009

_____/s/
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